PUBLIC HEARING

before

ASSEMBLY HEALTH AND HUMAN RESOURCES COMMITTEE

ASSEMBLY BILL 3150 AND SENATE BILL 2571

(Prohibit distribution and sale of irradiated food)

June 15, 1987
Room 341
State House Annex
Trenton, New Jersey

MEMBERS OF COMMITTEE PRESENT:

Assemblyman Harold L. Colburn, Jr., Chairman
Assemblyman Rodney P. Frelinghuysen

ALSO PRESENT:

David Price
Office of Legislative Services
Aide, Assembly Health and Human
Resources Committee

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Hearing Recorded and Transcribed by
Office of Legislative Services
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Trenton, New Jersey 08625

New Jersey State Legislature
ASSEMBLY HEALTH AND HUMAN
RESOURCES COMMITTEE
STATE HOUSE ANNEX, CN-068
TRENTON, NEW JERSEY 08625
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June 1, 1987

NOTICE OF A PUBLIC HEARING

THE ASSEMBLY HEALTH AND HUMAN RESOURCES COMMITTEE ANNOUNCES A PUBLIC HEARING TO RECEIVE TESTIMONY CONCERNING ASSEMBLY BILL NO. 3150 AND SENATE BILL NO. 2571, WHICH WOULD PROHIBIT THE DISTRIBUTION AND SALE OF IRRADIATED FOOD.

Monday, June 15, 1987
Beginning at 10:30 A.M.
Room 341 of the State House Annex
Trenton, New Jersey

The Assembly Health and Human Resources Committee will hold a public hearing on Monday, June 15, 1987, beginning at 10:30 A.M., in Room 341 of the State House Annex, Trenton, New Jersey, to receive testimony concerning Assembly Bill No. 3150 (Kelly/Loveys) and Senate Bill No. 2571 (Dorsey), which would prohibit the distribution and sale of irradiated food. The purpose of this public hearing is to receive testimony only; the committee will not be voting on these bills on this date.

Address any questions or requests to testify to David Price, Committee Aide (609-292-1646), State House Annex, Trenton, New Jersey 08625. Persons wishing to testify are asked to submit nine copies of their testimony on the day of the hearing. The chairman may find it necessary to limit the number of witnesses or the time available to each witness.

ASSEMBLY, No. 3150

STATE OF NEW JERSEY

INTRODUCED SEPTEMBER 15, 1986

By Assemblymen KELLY, LOVEYS, Hendrickson, Felice, Zecker, DiGaetano, Assemblywoman Donovan, Assemblymen Moran, Genova, Zangari, McEnroe, Arango, Dario, Gargiulo and Assemblywoman Ogden

AN ACT prohibiting the distribution and sale of food processed utilizing radiation.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. R. S. 24:5–8 is amended to read as follows:

24:5–8. For the purposes of this subtitle food shall be deemed adulterated:

A. (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health, but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health**[**,**]** *;* or

(2) If it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of regulations promulgated by the Department of Health limiting the quantity therein or thereon to such extent as the Department of Health of the State of New Jersey finds necessary for the protection of the public health; or

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.
Matter printed in italics *thus* is new matter.

with filth, or whereby it may have been rendered injurious to health; or

(5) If it is in whole or in part the product of an animal which has not been inspected, and the meat of such animal passed as fit for food,

(a) by an official Federal inspector, or

(b) By such officer or person as shall be qualified for such purpose in accordance with, and in such manner as shall be prescribed by, regulations adopted by the State department, if such inspection is required by such regulations, or if it is in whole or in part the product of an animal which has died otherwise than by slaughter; or

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health*; or*

(7) If, during the course of its processing, it has been exposed to, or treated with, radiation as a means of preservation.

B. (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) If any substance has been substituted wholly or in part therefor; or

(3) If damage or inferiority has been concealed in any manner; or

(4) If any substance has been added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is.

C. If it falls below the standard of purity, quality or strength which it purports or is represented to possess.

D. If it bears or contains a coal-tar color other than one from a batch that has been certified under the Federal Act.

2. This act shall take effect immediately.

STATEMENT

This bill would deem irradiated food-food processed with radiation in order to preserve it—adulterated, thus prohibiting its distribution and sale.

The exposure of food to radiation causes chemical changes in the food. The "radiolytic" products so generated may, in large quantities, cause cancer, birth defects, or other disorders. While the radiolytic products produced by food processing irradiation

are believed to be too low to cause harm, testing has been inconclusive on this point.

It therefore seems prudent to prohibit food irradiation until studies of its effects on human health, including its effects not only on consumers but workers exposed to radiation and the impacts associated with the transportation of radioactive material used in the processing, are reviewed and found to be conclusive in favor of safety.

FOOD AND NUTRITION

Prohibits distribution and sale of irradiated food.

[OFFICIAL COPY REPRINT]

SENATE, No. 2571

STATE OF NEW JERSEY

INTRODUCED SEPTEMBER 22, 1986

By Senator DORSEY

Referred to Committee on Institutions, Health and Welfare

AN ACT prohibiting the distribution and sale of food processed utilizing radiation.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. R. S. 24:5–8 is amended to read as follows:

24:5–8. For the purposes of this subtitle food shall be deemed adulterated:

A. (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health**[**,**]** *;* or

(2) If it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of regulations promulgated by the Department of Health limiting the quantity therein or thereon to such extent as the Department of Health of the State of New Jersey finds necessary for the protection of the public health; or

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) If it is in whole or in part the product of an animal which has not been inspected, and the meat of such animal passed as fit for food:

(a) By an official federal inspector; or

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter printed in italics *thus* is new matter.

Matter enclosed in asterisks or stars has been adopted as follows:

***—Senate committee amendment adopted October 27, 1986.**

(b) By such officer or person as shall be qualified for such purpose in accordance with, and in such manner as shall be prescribed by, regulations adopted by the State department, if such inspection is required by such regulations, or if it is in whole or in part the product of an animal which has died otherwise than by slaughter; or

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health*; or*

(7) If, during the course of its processing, it has been exposed to, or treated with, radiation as a means of preservation, except that, this paragraph shall not apply to any spice so exposed or treated*.*

B. (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) If any substance has been substituted wholly or in part therefor; or

(3) If damage or inferiority has been concealed in any manner; or

(4) If any substance has been added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is.

C. If it falls below the standard of purity, quality or strength which it purports or is represented to possess.

D. If it bears or contains a coal-tar color other than one from a batch that has been certified under the federal act.

2. This act shall take effect immediately.

FOOD AND NUTRITION

Prohibits distribution and sale of irradiated food.

SENATE INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

STATEMENT TO

SENATE, No. 2571

with Senate committee amendments

STATE OF NEW JERSEY

DATED: OCTOBER 27, 1986

The Senate Institutions, Health and Welfare Committee favorably reports Senate Bill No. 2571 with committee amendments.

As amended by committee, this bill deems all foods, except spices, treated with radiation (irradiated food) as adulterated food and thereby prohibits the sale and distribution of such foods.

The bill amends R. S. 24:5–8 to include in the list of "adulterated foods," any food except spices which, during the course of its processing, has been exposed to, or treated with, radiation as a means of preservation. The sale, distribution or manufacture for distribution or sale of any food which is adulterated is prohibited under R. S. 24:5–1.

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ASSEMBLYMAN HAROLD L. COLBURN, JR. (Chairman): Our Notice of a Public Hearing for today's hearing reads as follows:

"The Assembly Health and Human Resources Committee will hold a public hearing on Monday, June 15, 1987, beginning at 10:30 a.m., in Room 341 of the State House Annex, Trenton, New Jersey, to receive testimony concerning Assembly Bill No. 3150 (Kelly/Loveys) and Senate Bill No. 2571 (Dorsey), which would prohibit the distribution and sale of irradiated food. The purpose of this public hearing is to receive testimony only; the Committee will not be voting on these bills on this date." And, of course, it did mention too to contact David Price, who is the nonpartisan aide, in case you wanted to testify.

For those who have not contacted him, but who think they wish to testify, there are slips up here to fill out, indicating your name and whatever organization you are connected with, or if you are just representing yourself, and generally whether you are in favor of the bills or are against them.

I want to tell you, also, that we have had some pretty spirited public hearings and Committee meetings down here. It is our policy that even though we severely disagree with each other, we treat everyone courtiously because the purpose, especially today, is to get information. So, even though you might really take terrible issue with someone, please be assured that they are as sincere as you are in holding their diametrically opposed point of view. I don't know that we have any sergeants at arms. I didn't think with this group that we were going to need any. State troopers we have all over the building, and things like that.

I have been waiting for Assemblyman Frelinghuysen. He is in the building, and I am sure he will be here later.

I am going to declare the public hearing open. David Price is our nonpartisan aide. He is the one who referees

everything and runs this. Bill Naulty is my personal aide, and Dave Johnson over here is an intern with the Assembly Majority Staff. The big fellow you will see come in and out is John Kohler. He is the number-one issues man on the Assembly Majority Staff. So, the public hearing is open.

I thought since Mr. Kelly sits next to Mr. Frelinghuysen in the Assembly we wouldn't have to wait for Mr. Frelinghuysen, because he listens to Kelly all the time. I would like to ask Assemblyman Kelly to present his-- I guess you better try to get up here. These microphones record the proceedings; they do not amplify. So, the first witness will be Assemblyman Kelly, who is the prime sponsor of the Assembly bill. Good morning, Assemblyman.

A S S E M B L Y M A N J O H N V. K E L L Y: Good morning.

ASSEMBLYMAN COLBURN: I sit right in front of him, by the way, so he is talking to me all the time, too.

ASSEMBLYMAN KELLY: First, I want to set the record straight. I am not a biologist; I am not a chemist; I am not a scientist; I am none of those. I am just an ordinary banker. However, in January, 1986, my office became aware of the proposed Food and Drug Administration rule to permit the irradiation of fruits and vegetables. At that time, my staff and I began a comprehensive review of the subject.

The original information received from the FDA and other proponents certainly seemed to make an excellent case for their position. According to these sources:

1) The safety of irradiated food is supported by 30 years of research;

2) Irradiation could reduce the use of pesticides and chemicals;

3) Irradiation could help to feed the world's hungry by increasing the food supply;

4) Irradiation is being used successfully world-wide; and,

5) Irradiation creates chemical changes similar to cooking.

Well, to all of that, it is hogwash. None of that is true. The reality is quite different. There is not 30 years of research to support the safety of irradiated food. In fact, there is no evidence to support the safety of irradiated food. According to an internal memo from a FDA committee that reviewed all available literature on irradiation: "Studies of sufficiently high quality" -- and I am quoting from it -- "to support the safety of irradiated foods which constitute major contributions to the daily diet for long-term use are not available." I think I am finished with that memo; if not, I will see that you get it.

ASSEMBLYMAN COLBURN: I have read everything you have sent me.

ASSEMBLYMAN KELLY: Later on, Drs. Louria, Tritsch, and Piccioni will elaborate on the FDA research.

As far as eliminating pesticides, irradiation is a post-harvest job. You don't do it before; you do it after. So, the farmers are still going to use their pesticides. As far as the irradiation being helpful to the world's hungry, I think you are familiar, Doctor, with the World Bank Report on "Poverty and the World Hunger of 1986." In that report, it says there is ample food to feed the world's hungry. The problem is politics and economics, not the shortage of food. In our own country, we have billions of pounds of produce and food buried.

Irradiation is not used world-wide. Some proponents reported last year that a billion tons of food were irradiated world-wide. First of all, a billion tons of food is minuscule, and secondly, most of that which was irradiated was spices. I'll eat a pound of pork chops, but I won't eat a pound of pepper. That is what they have done. They are not giving you all the facts.

A survey conducted reveals that very few countries actually irradiate food. The world community is waiting to see what Americans do. Irradiation produces chemical changes completely different from cooking, which is precisely the reason why Congress, in 1958, classified irradiation as an additive and not a process. Irradiation has been proposed to eliminate trichinosis in pork. The Center for Disease Control reported only 68 cases of trichinosis in the United States last year and, in addition, the Department of Agriculture has developed an inexpensive and accurate test known as "Eliza" to detect trichinosis, so we do not need irradiation to solve the trichinosis problem.

Irradiation has also been proposed to eliminate Salmonella in meat products. The USDA acknowledges that Salmonella is due to poor hygiene conditions in meat processing plants. The eradication of Salmonella through irradiation would require the construction of thousands of plant facilities. It is neither possible nor desirable to construct that many facilities to prevent the estimated 70 deaths per year attributed to Salmonella poisoning. It should also be noted — and, Doctor, you know this -- that even water can be responsible for Salmonella.

Numerous studies have been found for every proposed use of irradiation. Safe and economical alternatives are always available. Irradiation has been correctly referred to as a "cure in search of a disease."

Among the proponents of irradiation is the World Health Organization. In 1981, the World Health Organization and the International Atomic Energy Agency released a study supporting food irradiation. Dr. Sanford Miller of the FDA -- that is the Food and Drug Administration -- testified before a congressional committee on the problems with the WHO study. The FDA reviewed the study and rejected its conclusions. In

1984, the American Medical Association passed a resolution supporting food irradiation. My office contacted the AMA to inquire how they were able to determine that irradiated food was safe two years prior to FDA approval. Their response was that their position was based primarily on the World Health Organization's study, whose conclusions were subsequently rejected by the FDA.

International food technologists are also proponents of food irradiation. Food technologists deal with food coloring, processing, and preservation techniques. They have no expertise in toxicology or the safety of food. Other proponents include the public relations groups, like the Coalition for Food Irradiation, and the American Council on Science and Health, which masquerade as public health interest groups.

Through all of my lifetime, I can recall numerous times when a Federal agency erred to the detriment of the public. During World War II, in my own experience in the Pacific, we used DDT all over. We even subjected men to atomic blasts. In Vietnam we used Agent Orange. All of these things were permitted based on theories. Well, the theories backfired. We should learn from those mistakes, and require more stringent standards for proof of safety, rather than relaxing standards, which the FDA has done with food irradiation approval.

Today, Americans lead the world in health care costs. If our Federal health officials were doing their jobs properly, surely Americans would have the highest life expectancy in the world, and the lowest rate of infant mortality. In reality, we are twentieth in life expectancy and fifteenth in infant mortality.

As a legislator, I have taken an oath to be concerned about the citizens of the State. I believe today we will clearly establish beyond a reasonable doubt that the FDA acted improperly when approving food irradiation. We have the

obligation and the opportunity to ensure that no citizens of New Jersey will be subjected to this highly questionable technology. Thirteen of New Jersey's fourteen Congressmen, and Senator Lautenberg, have cosponsored Federal legislation to stop irradiation. I have just received a letter from Senator Bradley, dated June 5, informing me that he is going to cosponsor this bill that is going to prohibit irradiated foods.

I urge you at this time to listen to the experts who will follow me. I am no expert, but we do have experts who will testify before you. I hope they will convince you that irradiation is not for the United States, and not for New Jersey.

By the way, the State of Maine just took these bills and made them a law. It is a law in the State of Maine.

That is about all I have to say.

ASSEMBLYMAN COLBURN: Thank you. Are there any questions? (no response)

Senator Dorsey, you're sponsoring the companion bill over in the Senate.

S E N A T O R J O H N H. D O R S E Y: Yes, I am.

ASSEMBLYMAN COLBURN: What would you like to say?

SENATOR DORSEY: Thank you, Mr. Chairman, and Rodney. Let me make it clear to everyone that the inception of this bill, and the struggle, was begun by Assemblyman Kelly and his fine staff, who accumulated a tremendous amount of information and disbursed it. They did so well in furnishing that material to myself and my staff, Mary Ann Horan, that when the issue was rather vehemently debated and disputed in the Senate, we achieved a rapid release from that Committee, and we achieved a victory for these bills on the floor of the Senate about four months ago by a vote of 30 to 3.

Now, I will not begin to discuss the various technical aspects of the bill because, in support of Assemblyman Kelly's bill here today, we have a rather illustrious array of

scientists and doctors -- Dr. Piccioni, who testified on a number of occasions in connection with the Senate bill, Dr. Bernstein, Dr. Tritsch, Dr. Louria, Dr. Johnsrud -- all of whom have intimate familiarity with the scientific and medical aspects of this particular problem.

As Assemblyman Kelly alluded to before, this effort in New Jersey, led by himself, is not being done in a vacuum. It is an issue that has been now touched upon, and reacted to, by people all over this country and, indeed, in foreign lands. As he noted, 13 of our 14 Congressmen have endorsed a resolution which would ban the distribution of irradiated foods. There is the Waxman Committee in the House of Representatives, which is considering a bill similar to this, and I suppose most interesting from our standpoint as legislators, our bill was picked up by the State of Maine -- the Legislature in the State of Maine -- and, in a rather rapid fashion, was adopted and signed into law.

So, the concern about this is not isolated. The concern with this problem is widespread and, of course, as Assemblyman Kelly has also mentioned, the European legislatures -- the parliaments -- have also entered into this particular field.

Now, I suppose in this kind of a scientific and medical debate, nothing is ever totally conclusive. But I think it is conclusive, and will be shown to be conclusive, that as legislators our function is to protect the public. In that connection, I would ask that you think in terms of erring on the side of the safety of the health of the people of this State, rather than on the side of any private interests or profit.

With that in mind, I look forward to hearing, as best as I can going back and forth with the Senate Committee today, the fine experts which Assemblyman Kelly and his staff have arranged to speak here today, at some considerable loss to

themselves in terms of their time. Because of their devotion to this subject and concern with the public health, you will have a very extraordinary array of experts.

With that, I thank you for entertaining me so early. Thank you, Mr. Chairman.

ASSEMBLYMAN COLBURN: Thank you. Next I would like to call Dr. Donald Louria, I guess mostly because he and I have one degree in common, I think, and also I have heard a lot about him at the Medical School. Are you here, Dr. Louria? (affirmative response) Good morning.

D O N A L D B. L O U R I A, M.D.: Good morning. I will apologize at the outset. It turns out that I have prepared testimony that I will get to you immediately afterward, but I managed to leave it in the car.

ASSEMBLYMAN COLBURN: And who wants to go to that hot parking lot right now?

DR. LOURIA: I would like to talk about several aspects of food irradiation, and I would like to make it clear that I am neither a staunch advocate nor an implacable foe of food irradiation. I think it is an interesting technology. I became involved in it primarily because of an interest in new technologies and whether or not they should be adopted rapidly by the society, and how we make our judgments about what technologies to accept and which technologies to overlook. I would emphasize that I am a member of no organization. I receive no pay from anybody for my involvement in food irradiation. In my department at the New Jersey Medical School, no member is funded either directly or indirectly by anybody either in favor of or against food irradiation.

I would like to focus on two issues. One is the issue of safety, and the other is the issue of nutrition. In regard to safety, the Food and Drug Administration has adopted food irradiation based primarily on five or, depending on how you count them, six studies out of at least 2000 studies. They

initially reviewed several hundred studies, and selected these five or six as impeccable and worthy to make judgments upon.

Because of the obvious selection bias in picking six studies out of a very large number, it seemed to me appropriate to obtain those studies and have them reviewed by statisticians and epidemiologists who could truly be labeled disinterested; that is, who have absolutely no involvement or particular concern about the field of food irradiation. So, I obtained those studies. Three of them are interrelated studies in French; one is in the German literature; one the English literature; and one in the American scientific literature.

I took the two that were in English and, therefore, we did not have to be concerned about problems in interpretation related solely to translation, and I submitted each of those studies to my Division of Epidemiology and Biostatistics. They were reviewed individually and separately by five epidemiologists and biostatisticians.

What they found was that methodologically they were surprisingly flawed. Even if you disagree with the judgment we made, the fact is that solid, well-trained epidemiologists and biostatisticians obviously do not feel that the Food and Drug Administration selected impeccable studies.

What I will do-- What I did manage to bring was the review of those studies. Our first study was in food and cosmetic toxicology in 1964. Thirty male and 30 female rats in four successive generations were studied. The diet included wheat irradiated with 20,000 or 200,000 rads. The following problems were noted by my colleagues:

1) Both controls and those fed irradiated wheat were given vitamins. In part, this was "done to avoid the reproductive difficulties noted with other irradiated foods -- difficulties that were attributed to the destruction of Vitamin A induced by radiation." The quote is not from my colleagues; the quote is from the article itself. The use of vitamins

could dilute any treatment effect if vitamins were protected. The authors of the article themselves noted: "Consequently, in many cases, statistical comparisons were not possible. However, examination of the data intuitively suggests that differences have no real significance." My colleagues found that this was a major difficulty. Differences were found, but the small sample size may not have permitted statistically significant differences to be detected.

There were four litters that were all stillborn in the 200,000 rad group, but none in the 20,000 rad group, and one such litter among the controls. The authors dismissed this with the statement: "No explanation is apparent for this difference." That is hardly an endorsement for irradiating foods that people around the world will eat.

It should be noted that 2000 rad is in the range for most foods to be eaten by humans, not 20,000. As a matter of fact, there is an interesting discrepancy in the article. They say four litters died totally in the 200,000 rad group, but when you look at the table on which my statisticians based their data, they only list three of those litters. They have apparently lost one litter, in which they say in the article, "All of the animals died."

The fourth point is that there are concerns about the overall stillbirth rate in litter size. The stillbirth rate in the 200,000 rad rats is more than double, a difference that is highly significant. They said it was not significant. When my colleagues recalculated the data, they found them highly significant. Average litter size in one generation with older animals was substantially less in the 200,000 rad group, suggesting the possibility of significant adverse effects among older animals. Additionally, it must be remembered that man has a much longer life duration; therefore, must longer exposure time.

Five, other statistical techniques could have been used that might have detected statistically significant differences. Conclusion for this study: This cannot be considered a flawless study on which to make major judgments. It raises concerns, rather than documented safety. Indeed, my own judgment is that this study does not show safety, and suggests that food irradiation at that dosage for those animals under those circumstances was, indeed, dangerous.

Study number two that they looked at, chronic toxicity studies on irradiated beef stew and evaporated milk. This was published in "Toxicology and Applied Pharmacology" in 1965; again, one of the studies used by the FDA. Rats and dogs were fed supposedly irradiated foods, but in point of fact it is interesting that we are given no data on whether those foods were actually irradiated. They were received from elsewhere, and were assumed to be irradiated. The statistical methods are not at all made clear. Out of eight control dogs, one showed abnormalities when they sacrificed the animal after the two-year feeding study.

One, five out of the 16 given irradiated foods in the two-year feeding program had some defects, defects such as enlarged glands and increased size of the spleen, and, almost inexplicably, the authors treat this dismissively as if having enlarged glands and an enlarged spleen was totally insignificant. Now, in point of fact, they may have been right, but surely one cannot disregard the findings of their own study. Those findings are actually quite significant; that is, abnormalities in the dogs given the irradiated food at least twice as frequently as found in the unirradiated animals.

This study lacks statistical power because it of the small numbers. The rat study looks reasonable, but one of my colleagues pointed out that the high mortality among rats fed evaporated milk in general, make conclusions virtually impossible.

Conclusion: This study raises many problems. It does not strongly support the notion that irradiated foods are safe.

The French studies were read by an internist at the New Jersey Medical School, who felt that their main problem was that there were small numbers of animals. These are three interrelated studies on irradiation of legumes, rice, and onions. The German study was translated by one of my technicians, and has intrinsic in it some findings that I think relate to the second issue I will bring up, namely depletion of nutrients.

In summary, if these are the five studies that the FDA has used and based its conclusions about safety and its willingness to effect implementation of the technology on, then on the basis of these studies alone, that technology should be stopped until there is more careful evaluation of the data. And, as I said before, these studies, when reviewed, hardly give any comfort to those advocating food irradiation.

One other point I think I would like to make in view of these studies and comments that have been made publicly is, there is, as you all know, a study in India on malnourished children, in which the children were fed irradiated grain, and then appeared to develop some chromosomal abnormalities. This study has been attacked methodologically. I am sure there are major methodologic flaws, and recently it has been suggested in an article I read, that an as yet unpublished study among young Chinese persons totally controverts the Indian study and makes it unnecessary to investigate further. This is absolutely not true.

The Chinese people were young, were healthy, were fed irradiated food for 90 days. They did not show chromosomal abnormalities. What the Indian study says is that it is absolutely obligatory, before unleashing this technology, to repeat the studies on more people, not just one other study, but more human studies in which included are: a)

undernourished children, or undernourished adults, and b), related to the findings that one of my colleagues pointed out in the data I just quoted, studies in older people. After all, if food irradiation is being touted as saving the world nutritionally by increasing shelf life, then it is clear that the food will be given to a substantial number of people in this world, as you all know, in the billions, who are undernourished, and it will be given to the increasing population of older people.

The Chinese study in no way approaches those issues and, therefore, in no way controverts the Indian study. My understanding is that the Canadian Parliament is now so concerned about those studies that there is a recommendation to ban irradiated food based on those. Once again, I would emphasize that it would be totally improper to allow the technology to be u ilized without a very careful reassessment of the potential for chromosomal damage in multiple groups.

The third point relates to nutrient depletion. Now, I am no expert on that, but I can read. There is article after article after article that says that if you irradiate the food, there is vitamin depletion, particularly Thiamine, Vitamin E, and Vitamin C -- Vitamin E, which is potentially very important in reproduction. It is interesting that although the Food and Drug Administration appears to treat this dismissively, two of the five studies that they cite for their permission to continue and to implement the technology, focus on nutrition. In one of the two studies in English that I cited, the author starts by saying: "This is a reproductive study, and because of the known deleterious effects of radiation on vitamin content of irradiated foods, we are giving all of the animals vitamins." So, obviously, they -- even if the FDA doesn't -- acknowledge that there is significant depletion.

The other is even more interesting. The German study looked negative, but when you looked at the data, it turned out

that after one year -- in successive generations -- that at one year the irradiated animals were deficient in weight, and the mortality -- the deaths -- in litters at 28 days was substantially increased. So, the German investigators said, "We know why these abnormalities happened. They happened because the irradiated foods that we fed them were Vitamin E depleted," and they showed they were Vitamin E depleted. Then they gave large amounts of vitamins, including Vitamin E, and the abnormalities disappeared.

So, it is absolutely clear that irradiation has the capacity to damage food nutritionally. Now, I submit that that is very dangerous. Furthermore, as you know, there are more recent data suggesting that if you irradiate food, and then treat it further -- cook it, thaw it, freeze it -- that that may markedly accelerate the damage to the food as a consequence of the prior irradiation.

Now, if the proponents say, "We are going to feed the world with food because we will have longer shelf life," then if they have longer shelf life, but the foods they give are nutritionally deficient, then what is the purpose of having longer shelf life? Besides, my suspicion is that the American public would not look kindly on eating foods that are deliberately deprived of their nutritional content.

There are three more points that I would just list without going into details. One is that if we approve this technology, it is clear that there will be large numbers of factories. That means there is going to be a lot of cobalt and a lot of cesium that is radioactive being transmitted, or transported on our roads. This is obviously of concern.

The second point is that those factories will have the capacity of contaminating the environment. And, surely it is clear from what has happened in the State of New Jersey over the last few years with the three initial plants, that the record in regard to the environment is absolutely atrocious.

Now, if we have a lot more plants, who is going to monitor those plants? Surveillance of those plants will be less and less effective and intensive, solely because of large numbers. After all, we already have problems with contamination in this State. We have a radon problem. I think we better think very, very carefully about adding a technology that has already been used to a limited degree in the United States, and has a track record of contaminating the environment with radiation.

A sixth point is, you know, we have sophisticated techniques. What I keep asking the food irradiation people is, if you are trying to persuade our society to adopt this new technology, why is it that you have not given us proper computer models as to how effective it is going to be? We have an idea about maldistribution of foods. We have an idea about the amount destroyed by rodents. We have an idea about the effects of corruption. These can be put into a computer model -- imprecise as it may be -- to at least give us a ball park estimate of whether we are talking -- if we irradiate foods around the world -- whether we are talking about a 5% improvement potentially, or a 10% or a 20% or a 50% improvement in caloric delivery to individuals. I think it is incomprehensible that we have no such models with the technology that has been explored for this long a time.

The last point relates to something that I think we all have to take into consideration. The food irradiation industry says, "This is a marvelous technology. We are going to benefit everybody. In the process, we are going to make a lot of money, of course, but that is secondary. The point is, we are going to help the world nutritionally." If that is true -- is that is true -- then why is it that efforts are being made sedulously to be sure that two years from now the American public will not be able to recognize that a food is being irradiated? If it is such a good technology, shouldn't they want, on every label, "Your food has been irradiated"?

Instead, as you know, they want some sort of nondescript symbol, knowing full well that very soon the American public will not know which food has been irradiated and which food has not been irradiated. I think that is totally improper. I personally think that before even considering allowing the irradiation of foods, there ought to be a referendum in New Jersey, and there ought to be a resolution nationally, and we ought to let the people decide whether or not they want to eat irradiated food, especailly since we have alternate technologies now available to keep food safe.

In summary, the FDA studies do not document safety. The safety issue has not been resolved, and it is just that simple. The issue of detriment to the nutrient value of the food is a real and major issue. Although I am not against the technology as a new technology, and I think it possible that in future years I could support food technology, today I speak as strongly as I can for banning irradiated food in the State of New Jersey. I think to do anything else at this state of our knowledge, with the concerns I have delineated, would be -- I don't want to use emotionally tainted words -- but I do really believe that to do so would be appalling and would be irresponsible.

Thank you very much. (applause)

ASSEMBLYMAN COLBURN: Dr. Louria, I would like to ask you, in other parts of medicine, it seems to me when major research is undertaken and the results are published, a lot of institutions look over what has been done and, you know, you read a lot of comments -- for example, in the "New England Journal of Medicine," pro and con articles that have appeared there. Were there efforts on the part of major institutions and good research groups to confirm any of these studies that the FDA has used in support of allowing irradiated food?

DR. LOURIA: Well, that is a good point. I think what happened-- I can't really answer your question, because I don't know all of the studies. There are over 2000 studies.

ASSEMBLYMAN COLBURN: I know there is a huge number of them.

DR. LOURIA: Right. Some of those may, indeed, have been in reaction to the FDA, but I think that is impossible actually, because the FDA decision is relatively recent. What I think happened was, people did not look at the FDA studies. People said, "Isn't it funny that they would approve it on five studies in theoretical calculations?" But I don't think people looked at it.

When I got involved in this -- it is an interesting sideline, and I don't want to take any length of time -- but I'll tell you, when I got involved in this -- and it was not many months ago -- it was a public debate. Before the debate took place -- and I had never spoken publicly -- my school -- my dean -- was sent a letter by one of the proponents, indeed a very vocal proponent who testifies before a lot of committees -- this Committee, too, I think -- which said, "This man has no right to appear. Do you approve of it? What has he done in the field of irradiated foods? Do you not worry that your Medical School is going to be tarnished because he speaks publicly?" This never happened to me in all of my years in academic medicine. In thinking that over, if I hadn't been so angry about it, I would have sent back a gentle letter to them, saying, "Look, in a new technology such as this, who should speak? If the proponents speak, people who stand to make a lot of money, or have some other proprietary involvement, that is biased. If the opponents who have formed groups speak, they can get fanatical in their opposition, and be unwilling to look at data that may be perfectly acceptable. Don't you really want academic institutions, which have no stake in it individually, or as institutions-- Let them look, in a

dispassionate fashion, at the data." When I went to the debate, I found that nobody had the five studies. I was staggered. Here we are talking about FDA approval, and nobody is talking about the specific studies.

So, we said, "We've got to get the studies. We have to look at them." I think your point could not be more important. I think it would be a very good idea to get academic institutions to do it, with a caveat. They have to be very sure to look at where the funding for that institution derives, because we are susceptible to biases, and if we are funded directly or indirectly by either proponents or opponents of a technology, there is a tendency for at least subconscious bias to be injected. That is why I liked our unit doing it. I mean, there are other academic units in New Jersey that could do it for you, but the people I gave it to-- I doubt that any one of the five statisticians and epidemiologists who read the studies had ever read a single study on food irradiation. All they looked at was methodology.

ASSEMBLYMAN COLBURN: Thank you. Thanks a lot. I understand that Dr. Solberg has to get a plane. If you were to testify now, would that get you to the plane, Dr. Solberg -- whom I don't know? (affirmative response) Okay, why don't you come forward?

I want to warn the group that they might not wish to applaud, but I would rather that you didn't hiss this gentleman. Please be kind. Good morning.

D R. M Y R O N S O L B E R G: Good morning, sir, and good morning to the members of the Committee.

I appreciate the opportunity to be able to appear before you. I think before I start, let me at least say that I am not a toxicologist. Everyone is giving disclaimers here, so I will give my disclaimer. I am not a toxicologist; I am not in the employ of any radiation proponent company or the like. I am a professor of food science, and I am the Director of the

Center for Advanced Food Technology at Cook College, Rutgers University.

Let me say that I started-- In terms of credibility, I started radiation research in 1954, when I returned from the Korean War, at MIT, which was the center of research in food irradiation. My Ph.D. thesis was the growth support potential of irradiated foods for microorganisms of public health significance, and public health significant microorganisms are, indeed, my area of expertise. It is to this point that I will spend the major part of my presentation.

In 1964, for those who are concerned with my desires for wealth, I gave up the industrial regime, and entered into the university at a 20% pay cut, and I think I have suffered ever since pay-wise, but never in terms of my mental attitudes and my self-satisfaction.

I think we have to look upon radiation of foods, we have to look upon radiation sources, as sources of energy. And, as sources of energy, they must be treated with respect. All the sources of energy we deal with must be treated with respect. The sun, if improperly used, causes cancer. The sun, if we protect ourselves adequately, provides the nourishment and warmth and growth of food that we need to survive. Fire, if improperly treated, if not given proper respect-- Mrs. O'Leary's cow showed us what it could do; it destroyed a city. But, we do not ban it. Electricity -- another source of energy. We let high voltage lines cross over our heads all the time, we let it enter into our houses, and we know it can be harmful to us, but if we respect it, we can deal with it, we can live with it, and we can get the benefits of it. So, food irradiation sources are risks, for sure, but they can be treated with respect, and they will then be safe.

As an energy source, they pretend to benefit many. If we consider that one of the greatest fears which people have about irradiation is that it causes cancer, if we look on the

other side, radiation is used to treat cancer. It is a treatment that works. It works because of what it does.

Let's turn our attention to food, though. What does irradiation of food do? First, it destroys microorganisms -- molds, yeasts, bacteria. Second, it inactivates growing cells, and this is really what it does in cancer cells. It takes those that are growing faster and preferentially destroys them. That is the way in which it can be used to our benefit. In plants it will do the same, and that is why it prevents sprouting. It selectively inhibits those cells that are likely to sprout. It inactivates insects. It inactivates parasites. It breaks down complex materials to make them, in some cases, more digestible and more available in our food supply.

What does irradiation not do? It does not produce unknown chemicals that are not present in any foods. These are the familiar URPs we have all heard about, the unique radiolytic products, and I am sure you will hear more about radiolytic products. There are no unique radiolytic products. These are figments of statisticians' imaginations. If you take and calculate out how many molecules there are being exposed, and how many possible changes there can be, you come up with a number that says there is something unique, but there are none that have ever been found, because one of the greatest searches we have had since food irradiation was conceived of, has been to find a unique radiolytic product which we can use as a marker to tell us if the food has been irradiated, and how much it has been irradiated. No such thing has been found, even in the latest studies which are being carried on.

Irradiation does not destroy the nutritive value of proteins, carbohydrates, fats, minerals, or any of the vitamins as well. But diets are not made up of irradiated foods alone. Diets are made up of mixtures. Many foods today which are processed -- many foods which we use today -- we supplement medically with vitamins; we supplement from a commercial point

of view with vitamins, because we know this is the way in which we can make the food supply better for the humans who consume it.

Now, what can irradiation of food do for us? What is the bottom line? The bottom line is quality of life -- public health safety. Reduce waste and, therefore, reduce cost; provide higher quality products, in terms of the flavor, in terms of the acceptability, in terms of the appearance, in terms of the things that make people want to eat. For the nutrition of foods that do not get eaten because they are undesirable in appearance, or odor, or whatever, is not nutrition at all. There is no nutrition in the food we reject.

All foods will not be irradiated. That was a panacea that when I entered into graduate school we dreamed of, but we very quickly learned that only those foods that will gain significantly and be economically feasible, only those are the ones that will be irradiated, and they are not great in number. They will continue to be developed perhaps, but there are certain things we must do, one of which appears in the rule making -- in the legislation that has been proposed; that is, the exemption of spices from the rule making. The reason you exempted them is that there is no better way of making spices serve as something you can add to food without contaminating it, without creating a source of inoculation of potentially harmful microbes.

Let me just quote from Commissioner Young's -- of the FDA -- recent article in "The Environment News Digest," in which he says: "Two FDA scientists estimate that roughly one-third of all the diarrhea episodes in the United States, somewhere between 24 million and 81 million cases annually, are of food-borne origin. The costs of these episodes, in terms of patient illnesses, medical expenses, and lost wages, is staggering. They produce substantial sickness and amount to billions of dollars each year. Diarrheal disease, often viewed

as a short-term nuisance for most of us, can bring death to certain vulnerable groups -- to the very young, the very old, and those with compromised immune systems. Recently, we have seen food-borne pathogens bring severe and often fatal complications in high-risk populations, such as pregnant women and fetuses infected with Listeria monocytogenes. Today we know, or suspect, that some pathogens associated with food may cause or trigger certain chronic rheumatoid disorders, such as arthritis, Reiter's syndrome, and ankylosing spondylitis. By influencing nutritional status and immune functions, food-borne pathogens may play a role in other disorders, such as respiratory infections. In effect, the toll in human suffering from food-borne illnesses may be far greater than any of us might initially suspect.

Why do I bring this to you? I bring this to you because we have been trying to find ways in this society for many, many years to eliminate these food-borne, illness-causing microorganisms. There have been episodes and dealings with these illnesses, and we can pick Salmonella as the one that is the most popular. The Salmonella cycle, as it has been envisioned, has not been stoppable. Nobody has stopped it yet, in no country, even under very controlled conditions. The only hope will be a secondary intervention, as I like to call it, putting up a hurdle in the system for that microorganism, and for its very close relatives, some of whom I have named in this reading.

It is irradiation, not at the levels that this legislation is trying to ban, but at the next level -- 10 times as great -- which is truly the important thing in terms of providing the public with the safety it deserves in its food supply.

I think we can follow a little bit further on this in terms of an article that quotes Michael Stiles of the University of Alberta in Edmonton. Michael Stiles is a

researcher whom I met at a recent appearance when I was asked by the Canadian Food and Drug Directorate to come up and talk to them about botulism and food processing. Michael Stiles says that perhaps the clearest trend is that more and more types of microbes are being recognized, at least for their potential role as food-borne pathogens.

As the family of Enterobacteriaceae has expanded -- and he notes 22 genera and 69 species now -- the faction suspected of causing food-borne diarrheal disease has also grown. Again, this is an area that only food irradiation, under presently known technologies, will be able to stop.

Perhaps you have all seen the "60 Minutes" documentary on Salmonella. While that was directed toward the Inspection Service, what it really said was, "We cannot stop salmonellosis by inspecting safety into food. Safety inspection into food is not feasible. We must do it by a process that works. That is the only route we have.

I think I would close simply by saying that I urge you to give the citizens of New Jersey an opportunity to have a safe food supply. I urge you-- (audience reaction) That is what we all want, in spite of the snickering here.

ASSEMBLYMAN COLBURN: Please, folks, let's--

DR. SOLBERG: I urge you not to provide the citizens of New Jersey with increased costs for their food supply. I urge you not to make New Jersey an isolated situation in the United States with respect to industrial competitiveness, and I urge you to give the citizens of New Jersey their best shot at healthy living.

Thank you.

ASSEMBLYMAN COLBURN: Thanks a lot. In the case of Salmonella, I remember when they banned the little red-eared slider turtles because they carried Salmonella. Do you remember them? (no response) We used to have them in our aquariums when I was a kid -- little green turtles. They were called red-eared sliders.

DR. SOLBERG: Right.

ASSEMBLYMAN COLBURN: And they brought Salmonella to us. Don't we kill Salmonella by cooking?

DR. SOLBERG: Yes, we do.

ASSEMBLYMAN COLBURN: If we cook something thoroughly. What happens if you scramble an egg?

DR. SOLBERG: Well, if it is loose, you may not have done the job. However, the biggest problem is not in what you cook, but in what you don't cook; that is, if you bring in poultry-- No matter how much education you try to give the consumer, or the people in the shops and stores where they handle the materials, or restaurants, no matter what you try to teach them, there is carelessness which allows the areas that were touched by the raw material to then come in contact with foods that are not going to be heated.

ASSEMBLYMAN COLBURN: Okay. Then, in the butcher shop, some of the people who handle them, might not wash their hands after they cut a chicken, or something.

DR. SOLBERG: Right, precisely.

ASSEMBLYMAN COLBURN: Okay. Did you want to ask anything, Rod? (negative response) I have another thing I want to ask you. These radiolytic products-- I guess they are breakdown products, aren't they, of exposure?

DR. SOLBERG: Right.

ASSEMBLYMAN COLBURN: Now, they are not all ions, or are they?

DR. SOLBERG: Well, they may be formed as ions, but they then become stable products.

ASSEMBLYMAN COLBURN: Okay. You said there were no unique ones. I had read the term unique, not only in what Assemblyman Kelly gave me, I think, but in other things I received from other sources. So the term unique, so far, you think is a misnomer?

DR. SOLBERG: Yes. I would say there are breakdown products.

ASSEMBLYMAN COLBURN: Yeah, but they are not unique?

DR. SOLBERG: Some of them are good; some of them--

ASSEMBLYMAN COLBURN: Yeah, but they are not uniquely due to radiation?

DR. SOLBERG: That's right.

ASSEMBLYMAN COLBURN: Okay. Are they found in other-- Like, if you just cook a raw food, do you get--

DR. SOLBERG: Many of them will be formed in foods during other processes. Many of them are present naturally in foods, because there are breakdown mechanisms in systems within the food.

ASSEMBLYMAN COLBURN: So, they become a stable compound, maybe what, a ketone, or some type of amino acid, or--

DR. SOLBERG: A chemical compound of some type, yes.

ASSEMBLYMAN COLBURN: Then the question is whether those things are harmful in themselves.

DR. SOLBERG: Yeah, but the point I have tried to make is, none of these are present that are not already present in our food supply, and that we are not creating a giant burden of them upon the populace, because people are not going to exist on irradiated food alone. It would be a small component of your diet.

ASSEMBLYMAN COLBURN: I was going to ask you also what I asked Dr. Louria: I wonder how far we have gone in trying to verify the studies that were used to justify irradiated food -- the irradiation of food and the use of it?

DR. SOLBERG: I am not sure I understand the question.

ASSEMBLYMAN COLBURN: Well, see, what I said to him was, at least in medicine most of what I thought I was being exposed to-- When a study of importance is done, all kinds of institutions criticize it; you know, they analyze it, challenge it. You see debates in the journals. They call each other dirty birds sometimes, and everything else.

DR. SOLBERG: I am not sure. I do not know. Those are not journals that I read--

ASSEMBLYMAN COLBURN: Me either.

DR. SOLBERG: --that those things have appeared in. But I do suspect that they are referee journals, which means that the article first goes to a group of peers to be reviewed.

ASSEMBLYMAN COLBURN: An editorial board, yeah. That's true.

DR. SOLBERG: And then it is available to the readers, and there is, undoubtedly, a Letters to the Editor section in each of these journals. So, I would suspect that these publications have had every opportunity to be reviewed and debated.

ASSEMBLYMAN COLBURN: Okay. Thanks a lot.

DR. SOLBERG: You're welcome.

ASSEMBLYMAN COLBURN: Let's see, who's next here. (Dr. Tritsch walks up to converse with Chairman) It's a funny thing, I was going to call Dr. Tritsch next because he comes from Roswell Park, and they have a good dermatology residency at the University of Buffalo. That is why you were going to get called next anyway, Dr. Tritsch, but you say you have to get back to Buffalo? (affirmative response) Well, I certainly thank you for coming down here. Will you please proceed?

D R. G E O R G E L. T R I T S C H: Thank you very much. My dean also received a letter urging my institution not to have me present this information to the public. I don't normally perform in public.

ASSEMBLYMAN COLBURN: You're safe in New Jersey.

DR. TRITSCH: Well, hopefully. I would precede my remarks by saying that I speak for myself, not for the Roswell Park Memorial Institute at the State University of New York, or the New York State Health Department. My opinions are my own, and my own alone.

I am opposed to the consumption of irradiated food. There is abundant evidence in the scientific literature that the condensation products of the free radicals formed during irradiation produce increases in carcinogenesis, mutagenesis, and cardiovascular disease. I will not address, as Dr. Louria did, the reported destruction of vitamins and other nutrients, because I feel I can supplement my diet intelligently to overcome this difficulty. But, I cannot protect myself from carcinogens and other harmful entities placed into my food, which I am unable to remove or protect myself from, and trade this for a possible increase in the incidence of malignant disease one, two, perhaps three decades in the future.

I am accustomed to teaching school, so I am going to give a little seminar to you here. I brought some slides so that the audience can follow along with my presentation.

I will begin by illustrating actual cases of how irradiation works. Molecules are hit by high energy beams. All of my slides, Mr. Chairman, are shown in my handout. The very first slide shows what happens when you irradiate a single molecule of a fatty acid. You get a large number of free radicals. These free radicals react with other free radicals, so you get secondary particles. I am showing you this slide not for any particular purpose of looking at the actual molecule, but to demonstrate to you the huge number of different molecules that one should expect to find. Later on I am going to show you where we find some unique radiolytic products.

Now, the next slide -- my second slide -- will show you a mass spectrum of a fatty acid. This is a single molecule, not a complex mix as you find in food. On the "X" axis you will see the mass number of the material we are talking about, and on the "Y" axis the relative amounts. You can see that the peaks have different sizes. If a single molecule were cleaved, they would all be the same size. You

would get a half, a quarter, a single fraction. But you see some peaks are huge as compared to others, which tells you there are secondary, tertiary, and many-fold condensation products of these free radicals. These combinations continue well after irradiation has stopped.

There is data in literature that shows you that the food will change during storage for many, many weeks, so that different doses of radiation will give you not just different amounts of a given material or radiolytic product, but different kinds. They will be qualitatively different.

Let me just give you a simple textbook example of the numbers that are involved. What do I mean by a lot or a little. Let's take water, which constitutes about 80% of most foods. If we hit water with 100 kilorads -- not a particularly high dose -- you will find, calculated entirely on theoretical grounds, six out of ten million bonds will be broken. That is a small number -- six out of ten million. Now, we can calculate further from this -- and I have this calculation in my handout-- If you look at one glass of water, which is about a quarter of a pint -- a very small glass of water -- a trillion trillion bonds will be broken. That is a big number, even for a State legislator. A trillion trillion is a lot.

ASSEMBLYMAN COLBURN: We're working toward it.

DR. TRITSCH: In a small glass of water, this is how many free radicals of ozygen you might expect.

Now let me talk about some specific studies. The first one I will deal with comes from 1986 -- not a very old study. This is particularly timely, because it deals with fats. I am reading on page 2 in the middle, but if you want to see the figures I am referring to, they are numbered the same way as the slides. Now, the American public is being advised to cut down on fats in their diets, particularly saturated fats, because we know these fats are related to cardiovascular disease. Indeed, the intake of polyunsaturated fats is

increasing in our diet. I am going to talk about what happens when you irradiate foods high in polyunsaturated fats.

Now, the next slide, please. (speaking to gentleman running slide projector) What happens there is that the benzo-pyrenes present in these foods increase enormously. The solid line shows you the separation. This is a chromatogram. The solid line is the irradated food; the broken line is the unirradiated control. You can see the three large peaks, the benzo-pyrene quinones, which are known carcinogens, increase appreciably in this sample of irradiated food. I will also direct your attention at peaks marked A and B in this chromatogram. There you will see nothing in the unirradiated food, and you see appreciable peaks in the irradiated foods.

I submit, Mr. Chairman, that this is a unique, or at least a radiolytic product right there.

The next slide will show you that this is dose dependent. You can see an approximate lineal increase in benzo-pyrene quinones as irradiation increases. The next slide will show you that in different foods, this is different. The last two bar graphs I am showing you are cod liver oil and mackerel oil, which are high in unsaturated fats. People tell you to eat lots of this stuff because it is good for your heart. These are precisely the foods that will increase in benzo-pyrene quinones. Corn oil, which contains lots of Vitamin E, is protected from this. Now, if I had corn oil later on after the irradiation, that is not going to help. If the Vitamin E is present during the irradiation, this vitamin will trap the free radicals. If you use saturated fats, like coconut oil -- shown in there -- there is a very small effect. The major effect of the irradiation of fats is on the unsaturated fats which we are asked to consume in greater amounts.

Now, there is another problem that is not addressed in this study. Incidentally, I document, at the end of my

presentation, the actual references, if you wish to get all of the details of this study. Not mentioned in this study is that once you treat these unsaturated fats with high energy beams, you are getting several cross link polymerizations. The best way to illustrate this is to tell you it is analogous to the drying of oil-based paint. You get a large polymer, which is not degradable by digestive enzymes. These polymers can be deposited like plaques, entirely akin to the deposition of cholesterol in our blood vessels, and can lead to elevated blood pressure.

Now, in the consensus statement, of which you have a copy, there is frequently quoted the document, "The Safety of Irradiated Food," mainly Publication 109. I am quoting directly from page 17: "In this research, several anomalies appeared in the test animals -- for example, hemorrhages, ruptured hearts, and vitamin deficiencies -- but these were related to feeding the test animals food they did not customarily eat, and not to treating the foods with ionizing energy." Now, hemorrhages and ruptured hearts bring to mind acute and very marked elevation of blood pressure. Furthermore, I would question initiating a study of feeding animals food they don't normally eat, and then attributing any adverse effect to this entity in the first place. If you are going to do this, let's do this thing right. This is one statement I would challenge you to find in the refereed scientific literature. This is not playing by the book.

So, in summary for this part of my presentation, it is the unsaturated fats which pose the greatest threat to irradiated food.

I would next talk about cold cuts -- food that contains nitrate. Now the next slide, please. You can see that irradiation of food that contains nitrate shows a marked decrease in the nitrate, with a concomitant increase in nitrite. Now show the next slide, please. The nitrite

increases as quickly as the nitrate decreases. We know that nitrite is mutagenic. It forms a very potent class of carcinogens called nitrosamines.

The next slide is a quote from a New Zealand article, which states that in New Zealand they do not allow more than 125 milligrams per kilogram of nitrate and nitrite, for just this reason. These are unequivocal carcinogens. No, they are not unique radiolytic products, but they are about as potent a carcinogen as you can find. I would prefer not to eat these if I don't really have to.

The last studies I wish to summarize have been talked about before. I am going to show you the actual data of the much quoted Indian study. This is an old study -- 1975. Here, five malnourished children were given wheat irradiated with 75 kilograms -- only five children. There were five controls, as well. This irradiated wheat was perfectly able to cause weight gain in these children, normal serum albumin, and normal hemoglobin. If you stop here, this is good nutrition. The children gained weight just the same way as the kids who got unirradiated wheat. So, on the surface, this looks great. However -- now the next slide, and this was the slide Dr. Louria was referring to -- these five kids who received the irradiated wheat all showed elevated polyploidy. I am going to tell you in a moment what I mean by this. Here you see four out of the five kids after four weeks of feeding showing an increased number of abnormal chromosomes. One of the children didn't. Now, you see, they are worried about this. They sampled that one child, I think every week. They had to take blood from him, culture the white cells, to see if polyploidy was found. This one kid was resistant. People differ in their resistance to carcinogens.

Another point of this slide is, as soon -- this obviously frightened them -- as soon as the feeding was stopped, polyploidy went to normal. After, I think, something

like 26 weeks, polyploidy was back to normal. I took the data from that publication, and I took the liberty of doing my own primative statistics. The last slide will show that this is indeed statistically significant. You can see that the probability is .02, which says that if you repeated this study, with any number of children you wanted to, there is a 2% chance that these findings would not be repeated, but a 98% chance that you would get the same results.

So, I would not agree with Dr. Louria. Please, let's not feed more kids this irradiated wheat. Five is entirely sufficient. Furthermore, this study was repeated on monkeys and rats, and the same thing was found. If you feed the stuff, polyploidy is found; after you stop feeding it for several weeks, polyploidy goes back to normal.

Let me tell you what I mean by polyploidy. This is a term that is bandied about, and I feel I owe it to you to show you what is involved. May I have the next slide, please? This slide is the normal chromosome picture. I chose a female just for argument's sake. You can see the 46 chromosomes that are normal in the female. Now, the next slide I am going to show you is the carrier type -- may I have the next one? -- of chronic myelocytic leukemia in the female. I challenge you to see a difference, but if your eyes are sharp you will see that in one of the chromosomes marked G22, there is a small arm missing in this slide, and it is added to chromosome 9. You are going to need sharp eyes to see this. I have a picture of it in the handout, if you would like to look at this. You have to look at it in some detail. A small change like this -- ostensibly small -- results in chronic myelocytic leukemia. This is an ominous change; it is an irreversible change.

Mongolism -- Down's syndrome -- results in trisomic G21; that is, you will see three G21 chromosomes. You do not need a large change in chromosomes to have a marked change in the expression of the genic.

Now let me show you the picture from the Indian article that shows you what these kids look like. Oh, I'm sorry, I guess I don't have a slide on this. It is in your handout. If you will look at Fig. 13, you will see -- these are not terribly good illustrations; they are hard to duplicate -- that the number is bizarre. It is towards the end. You will see a whole series of chromosomes. I believe it is Fig. 13 -- towards the end of the handout.

ASSEMBLYMAN COLBURN: Oh, yeah, okay.

DR. TRITSCH: You have to keep going, and you will see Fig. 13. If you look at these chromosomes, their shape is abnormal. The number is abnormal. This is a gross change. Polyploidy is nothing to dismiss lightly. In the same publication 109 -- of which you have a copy -- the statement is made, "Normal chromosomes 0% is impossible." That is nonsense. If you were to find an abnormal chromosome number -- shape in anyone in this room, I would say run, don't walk, and have yourself looked at in great detail. This is not a symptom to be dismissed lightly. This is clear-cut mutagenesis, and should not be simply dismissed.

I would remind you just for comparison -- again we are talking about numbers -- in the United States the highest form of cancer we have is lung cancer. In '82 to '83, the incidence was 80 out of 100,000. If you do your arithmetic, that is .08%. In these children, it was 80%. If you had asked me to design a study to feed irradiated wheat to children, and said, "Can we see something?" I would tell you, "You are going to have to feed at least 10,000 before you will see anything. To feed five children, I'll tell you, you are wasting your time. There is no chance whatever that you will see abnormalities in five children. This couldn't be that potent a mutagent." It turned out it is. I am surprised that it should be this potent. It is almost unbelievable. I would have told you, "Do the study with at least 10,000 children if you want to see

anything you can report." The fact that you saw it in five is really staggering.

I have mentioned that the same thing was found in rats and in monkeys. I disagree with Dr. Louria. Let's not repeat the study. Do not feed irradiated wheat to any more children. For heavens sake, I think we have had quite enough. This is as much as you need. The statistics are really quite convincing.

If you go back a little bit to the '60s, you will see that irradiated sucrose can be mutagenic as well -- mutagenic to human cells, as well as to plant cells -- again, looking at the chromosomes. If you look at the sucrose effect, you will see that it is perfectly normal nutrition. If you only look at nutrition, no problem with the sucrose. This becomes apparent when you look at the quantitative aspects of this. I have summarized these studies in the table at the very end of my handout. If you irradiate 280 grams of sucrose, you will find that you recover 263 grams of unchanged sucrose. Clearly there is plenty of good sucrose in there, all you need for nutrition. But, less than half a gram of formaldehyde was formed, and the slide that is on the projector now shows you the basis of the mutagenic effect of formaldehyde. It cross links out the genetic material DNA. We know that morticians and pathologists who deal with formaldehyde all the time have an increased incidence of cancer. Formaldehyde is nothing to play with.

If you look at the next slide, it will show you the Ames Test, which is a very well-known and respected test for mutagenicity and carcinagenicity. It will show you that whereas high levels of formaldehyde are clearly toxic, low levels are mutagenic when you get to 50 micrograms -- not milligrams, but micrograms -- per assay plate. Formaldehyde is nothing to take lightly. Furthermore, if you look at the table that summarizes these studies, you will see that about a gram of UV -- ultraviolet light absorbing materials is formed when

you irradiate sucrose. These materials were not analyzed in detail, but the only way you could get ultraviolet absorbing material from sucrose is if you have multiple condensations from the free radicals that you form by the irradiation of this molecule. The fact, again, that the irradiated sucrose is mutagenic, but able to support nutrition normally, raises a red flag. We can feed people and they will gain weight, but they are trading in one, two, three decades down the road an increased incidence of neoplastic disease.

I would say in summary that we have convincing and very acceptable evidence that irradiation does cause mutagenicity in experimental animals, in human culture cells, and in man himself, albeit in five Indian children. This is statistically significant. Just about every food contains carbohydrate. What I have shown you applies only to the foods I have shown you. If you are going to irradiate a papaya, or something else, as has been done, my data would not apply to this. You would have to look at each food as an individual.

If you are going to do this, let us do it properly and systematically, not arbitrarily. If you want to do this test, let us determine how much papaya, or chicken, or whatever you wish, the average human is going to consume in a lifetime -- not two weeks, not two years, but a meaningful period of time -- and take the free radicals condensation products formed in this amount, and let us test it with the Ames Test. This is a reliable, convincing test. It may be laborious, and perhaps expensive, but by no means difficult. The very last reference in my handout is an article in nature which outlines the economics and the sciences of testing materials for mutagenesis. This is an acceptable and clearly a feasible way of going about this. I am not saying it is easy. What I am saying is, if you want to take the trouble, you need to do this. I think the burden of proof has to be on industry to show that this is not as harmful as I am saying it is.

Otherwise, the studies I have shown you, Mr. Chairman, are really not only convincing, but statistically, unequivocally significant. (applause)

ASSEMBLYMAN COLBURN: Thank you. I would like to ask you about the ultraviolet absorbing compounds that result from irradiation of sucrose, as I understand it. You know, I am concerned about sun allergies as they affect my field of dermatology. Do you think we have run across any-- I guess we are not really eating sucrose generally that is irradiated.

DR. TRITSCH: I do not believe it is legal to irradiate sucrose.

ASSEMBLYMAN COLBURN: At the present time.

DR. TRITSCH: What I am saying is, if you irradiate sucrose, according to the article in the reference I have given you, you will get some materials absorbing the ultraviolet. Okay? This mean that you have gotten multiple condensation products. The way you are absorbing the ultraviolet means that you have conjugated double bonds. I am not trying to throw mumbo jumbo at you, but this means that from sucrose--

ASSEMBLYMAN COLBURN: Well, I am not 100% familiar with what you are saying, but I have a general idea.

DR. TRITSCH: Anyway, it is a large molecule. It means it is not just cleaving a sucrose at one point, but you are getting free radical and you get multiple -- not just one, five, perhaps ten condensation products. These are large, complex molecules.

ASSEMBLYMAN COLBURN: Do you think they are anything like light sensitizers that we encounter in medications?

DR. TRITSCH: I don't believe so.

ASSEMBLYMAN COLBURN: You know, any other place, the things that have to do with--

DR. TRITSCH: The only thing I am trying to say is, you are getting large molecules. I am not saying these ultraviolet absorbing compounds are carcinogenic.

ASSEMBLYMAN COLBURN: No, I know you're not, but this is like a separate issue.

DR. TRITSCH: It is a separate issue altogether. I believe in sucrose--

ASSEMBLYMAN COLBURN: Well, it is an important separate issue.

DR. TRITSCH: It is an important separate issue.

ASSEMBLYMAN COLBURN: It is not carcinogenesis, but it is light sensitivity.

DR. TRITSCH: Yes. I don't believe that what we are talking about here has anything to do with it, other than formaldehyde. I think the major mutagent in irradiated sucrose is formaldehyde. I don't know; this is intuitive. The UV absorbing materials that you find in irradiated sucrose, I do not believe are related to what would happen if you stood in the sun long enough even to give you melanoma or a squamosal carcinoma. I don't think this is related. It just tells you you are getting large molecules. It is a means for the scientist to look at this and say, "You are getting lots of condensation products." This is a complex issue. People really have not done the science to tell you what these compounds are. I would disagree, violently, that there are no unique radiolytic products. There certainly are. But, this is tough science, and for most people, not terribly interesting science. Somebody would have to pay me to do this, because I don't think this is sufficiently interesting science where I would have a student do a thesis on this. This is analytical natural product chemistry, and there are more interesting things I think I would have a student do than this. This is not to depreciate the importance of this fact. This would have to be done, I would think, as a contract, with someone saying, "Look, find this. We will pay you people so much an hour. Let's get to the bottom of this." This is not terribly exciting science in this day and age.

ASSEMBLYMAN COLBURN: Thank you. Thanks very much. Dr. Fey, do you want to come forward?

D R. M I C H A E L S. F E Y: Yes, sir.

ASSEMBLYMAN COLBURN: Good morning.

DR. FEY: Good morning.

ASSEMBLYMAN COLBURN: I guess it is still morning by three or four minutes. We will probably go right on through here. Mr. Frelinghuysen likes lunch, but it never bothers me much. He has been out to have something; I don't know what.

DR. FEY: Mr. Chairman, members of the Assembly Health and Human Resources Committee, and members of the public: My name is Dr. Michael S. Fey. I am an independent food industry consultant with more than a decade of technical experience in the field of food science and technology. I am a professional member of the Institute of Food Technologists, a worldwide professional organization consisting of more than 30,000 members from industry, the government, and academia.

I completed my doctorate at Cornell University in the field of food science and technology, with additional academic disciplines in microbiology and biochemistry. I developed and technically managed national market leading food brands with a Fortune 100 company, and researched, published, and practiced the technology of food irradiation as a Director of the Food Division at Radiation Technology, Inc.

As a former researcher of food irradiation technology, I had an excellent opportunity to review the existing world literature on food irradiation, review comments made by irradiation advocates and opponents, and experiment with the technology of food irradiation on hundreds of foods.

I, too, started my research efforts in the field of food irradiation with emotionalism, and healthy skepticism, but with an open mind. However, after reviewing much of the world literature, and after commercial research and practice of the technology, there is little doubt in my mind that history will

prove food irradiation to be one of the most important advances in dietary health since the invention of pasteurization.

Food irradiation has been researched over the last 40 years, perhaps more so than any other food process, despite a climate of intense emotional and scientific scrutiny. There is such a vast amount of literature on the subject that a library for food irradiation, called Pathfinder, has been formed at the United States Department of Agriculture's National Agricultural Library.

Today is just an example of the type of scrutiny that scientists and researchers throughout the world have been asked to address. And despite this intense scrutiny, the technology has been shown to be safe, effective, and publicly beneficial.

The issue we are addressing today is to prohibit the distribution and sale of food processed utilizing irradiation in the State of New Jersey. Let's focus on the issue of the technology of food irradiation, its safety, and its benefits and risks.

Opponents of the technology will undoubtedly bring up other issues to cloud the focus of this hearing, such as: wanting to halt the spread and proliferation of nuclear waste; the dangers of transportation of nuclear waste; the incidence of accidents at irradiation facilities; or the general increase in certain types of cancer and other evils in our society today. Dr. Louria did so towards the end of his presentation. Be aware, the names of many of the organizations these citizens represent indicate that their focus is not necessarily anti-food irradiation, but opposition to other issues. Food irradiation just happens to be related to one of their causes.

The issue we need to address today is, what are the benefits and risks of selling and distributing food processed utilizing irradiation in the State of New Jersey? And consequently, if we pass such a law, will we be violating the rights of our citizens to choose whether or not they want to purchase and consume foods that have been irradiated?

I would like to give you a little bit of background on food irradiation. In food irradiation, foods are simply exposed to controlled amounts of gamma energy, typically from the radioisotopes cobalt-60 or cesium-137, or from machine produced x-rays, or electron beams. it is physically impossible for foods to become radioactive, because there is not enough energy in the radioisotopes to induce radioactivity, and the energy output in the machines is limited by law.

Technically speaking, we irradiate food every day with microwaves, although we don't normally refer to microwaved foods as irradiated. Furthermore, the sun naturally irradiates all food with a spectrum of radiation including gamma irradiation and x-rays.

In the current bills -- S-2571 and A-3150 -- are we being asked to ban heat irradiation, ultraviolet irradiation, microwave irradiation, or machine produced electrons and x-rays? The way the bills were worded leaves too much room for interpretation. I don't believe a bill with such a nebulous interpretation should even be considered.

Let's look at the important issue -- the public health aspects of food irradiation. How many times this year can you remember having a short-lived stomach ache, nausea, fever, or vomiting? In many instances, these illnesses were caused by bacterial food pathogens, such as Salmonella and campylobacter, which occur naturally in our foods, or are introduced during processing and handling. Most pathogens present no danger until they grow in number, typically after inadequate refrigeration.

Despite all the efforts of the Department of Agriculture to ensure that both people at home and people in industry maintain care not to abuse the foods, these organisms still proliferate and cause problems. I am going to relay those problems.

Ms. Tanya Roberts, of the United States Department of Agriculture's Economic Research Service, estimated that about $1 billion could be saved in the United States economy each year, if fresh beef, chicken, and port were irradiated at low dose to eliminate pathogens. Savings were estimated from work loss due to illnesses, and actuary policy payments due to death resulting from food-borne pathogens such as Salmonella and campylobacter, which, by the way, are estimated to cause 4000 deaths and more than four million illnesses each year in the United States. That's Ms. Tanya Roberts.

From my review of data supplied by Dr. John Benett of the Center for Disease Control in Atlanta, I estimated about 17,000 American lives could be saved each year, and about 12.5 million food illnesses could be prevented if irradiation were used to pasteurize a wider variety of foods. Notice before we mentioned chicken, pork, and red meats. We did not include the fishes, eggs, and other products -- other food products. This could potentially amount to a cost savings of more than $4 billion to the U.S. economy.

But, hold on. FDA's Doug Archer and John Kvenburg estimate that 24-80 million cases of food-borne diarrheal disease go unreported each year, costing about $5-17 billion annually in economic losses due to medical care and lost productivity.

The numbers can be argued, but the point is that food irradiation pasteurization can save thousands of lives now, can prevent millions of food-related illnesses, and can offer billions of dollars in cost savings to our economy -- right now.

The consumer would notice no difference from the packaged meat products she normally buys, except that her food would be "pathogen-free," and would last up to two to three times longer, or more, in the refrigerator.

Irradiation can also be used as a safe alternative to ethylene oxide, a suspected carcinogen which, by the way, has

been banned in Europe, but is currently used to reduce bacteria in spices, herbs, and other areas. Use of food irradiation as an alternative to fumigation can save additional lives, reduce the incidence of cancer -- which we have been talking about today -- and save additional economic loss to our economy.

The technology is so versatile it can kill insects, eggs, and larvae in fresh produce, prevent sprouting in potatoes, increase juice yields, even sterilize complete meals without heating. High dose sterilized irradiated meals were eaten regularly by United States astronauts in space. I know, because I provided those meals to them.

Increased shelf life and an increased food supply can save additional billions of dollars in our economy, can help provide surplus food to starving people in Third World countries, and can help improve our negative balance of trade.

Let's talk about the safety of food irradiation. The safety and efficacy of the technology of food irradiation has been studied extensively by independent multi-disciplinary teams of scientists around the world. We heard today that there have been several studies done, and the FDA has only reviewed maybe six studies. I believe this is misrepresentation of fact. There is a complete library. FDA reviewed more than 800 studies. This has been extensively reviewed around the world by multi-disciplinary teams of scientists -- toxicologists, nutritionists, medical doctors, food technologists, microbiologists, and the like. There has been a lot of work done in an environment of intense scrutiny. The result is that foods have been approved for irradiation in more than 30 independent nations.

The World Health Organization, the Food and Agricultural Organization, and the International Atomic Energy Agency, in 1981, promulgated a regulation to the Codex Alimentarius and its 122 member nations. The regulation permits unconditional irradiation of foods to an overall

average dose of 10 kiloray as safe and effective. That dose is more than 10 times higher than the current one kiloray maximum dose approval for maturation inhibition of fresh foods in the United States.

Food irradiation has also been studied and reviewed by many independent organizations in the U.S. The technology is supported by the Food and Drug Administration, the Department of Agriculture, the U.S. Army Research and Development Program, the American Medical Association, the American Council on Science and Health, the Institute of Food Technologists, the Council for Agricultural Science and Technology, to name a few, and a multitude of academicians throughout United States universities and throughout the world.

The apparent risk of widely selling and distributing irradiated foods is that there may be ill effects resulting from the food irradiation process that we don't know about that may cause widespread harm to consumers, and we heard about that today. These ill effects have been alledged to come from unique radiolytic products, free radicals, mutant strains of bacteria, and the induction and detection of Clostridium botulinum. The destruction of the nutritional value of our foods has also been mentioned.

I would like to talk about these individually:

URPs: The substances alledged to cause ill effects have been labeled URPs, of which, to my knowledge, none have been found to date. If they were found -- as FDA has calculated -- they would exist in such low concentrations, on the order of a few parts per million, that their presence would cause no known ill health. For comparison, known carcinogenic pesticide residues can be found in our food supply at the parts per thousand level right now.

Free radicals: Free radicals is a term with a negative conotation that opponents use with regard to food irradiation. The term has been associated with cancer. It

describes an unstable molecular state in which a molecule seeks another molecule to give it molecular and energetic stability.

Free radicals are produced in irradiated foods when electrons are kicked out of orbit by gamma or x-ray energy. However, free radical formation is very short-lived. Within microseconds, free radicals reform naturally with their parentals, or as a very small percentage of the total, with other molecules in the near molecular vicinity. To illustrate these changes in perspective in irradiated foods, there is a slight to moderately noticeable organoleptic difference in foods at high doses, and an undetectable difference at low doses. Since the human senses are acutely sensitive to chemical changes, this amounts to very little chemical change at low doses. Instrumental analysis confirms there are minor, insignificant changes. What you see and taste, is what you get in a food. This is important, because we are looking for large changes that take place in some of these low-dose irradiated foods that are currently approved. They are so minute, our senses, which are far more accurate in a multitude than many instruments acting independently, would detect these changes, and they do not, because they are not there.

For example, vitamin losses -- which is a good tag -- are small to negligible at low irradiation doses, and either comparable or lower after irradiation processing than thermal processing to an equal microbiological destructive value. So, what we are saying here is, irradiation does destroy nutrients, but it does it comparably to thermal processing, or better.

On the other hand, gamma or x-rays have a detrimental effect on the DNA of living organisms, such as insects, bacteria, and viruses. One deviation of free radical formation with its parental in a vital part of the DNA of a living system may be enough to cause dysfunction and kill the organism. Obviously, the greater the dose, the greater the chance that this gamma beam will cause a free radical formation, and the greater chance for killing the organism.

I think in looking at what Dr. Tritsch has mentioned, we need to talk about what dose those studies were conducted under, and they were conducted in a system. People do not normally just consume straight sucrose. People consume foods which are chemical soups. These chemical soups contain other chemicals, natural antioxidants, if you will, which tie up free radicals, and free radicals are produced in canned products as well. You talk about carcinogens in food; you want a carcinogenic-free food. Barbecued chicken and barbecued meats are highly carcinogenic. They contain polycyclic aromatic hydrocarbons, but we consume them. Our bodies have adapted over time to handle minute carcinogens. Tomatoes contain tomatine; potatoes solanine -- all carcinogens. You've got spices, which contain many toxic substances -- mustard, very toxic -- but our bodies are capable of handling these things in small quantities. As long as we eat a good, varied diet, our bodies will be able to handle any kind of small, minute toxic residues like that.

Other risks mentioned by the opponents of food irradiation are the possibility for new irradiation-induced mutant strains of bacteria or virus, and a hypothesized increased risk of potentially lethal food poisoning due to induction and possible lack of detection of toxin produced by Clostridium botulinum, which is botulism.

Foods are irradiated once, and not re-irradiated, as required by the FDA. A one-time irradiation essentially eliminates the chance for developing a surviving mutant capable of adapting to greater doses of irradiation. The concern that a new mutant strain will develop that can cause harm to mankind is no greater than the concern that other mutagens, chemicals, sunspots, the moon, the stars, or other processes of nature may cause.

Risk of botulism: There is little evidence in the literature that low dose irradiation can induce the growth of

Clostridium botulinum due to decreased competition from other microflora. Furthermore, low dose irradiation can easily destroy the viable cell state of Clostridium botulinum, which has been reported at its highest occurrence naturally in comparatively low numbers, at 10 organisms/gram in fish. And, other combined technologies -- these are food technologies -- such as refrigeration below 3 degrees C., acidic environments, low moisture environments, and atmospheres containing oxygen can prevent Clostridium botulinum growth.

The Clostridium botulinum concern should be no greater than the concern for currently available vacuum-packed fresh pork found in the refrigerated meat section of the supermarket, and perhaps less concern because low dose irradiation will kill viable C. botulinum cells.

At high doses, foods can be exposed to irradiation doses equivalent to the 12D, or 12 decimal log reductions multiplied by the amount of gamma energy required to reduce the population of Clostridium botulinum -- or any other microorganism -- tenfold. So, you are giving it a dose that reduces the population tenfold, and to get the 12D dose, which is the criteria used in the canning industry, you do 12 times that dose, and then do that with heat -- 12 times that amount of heat to reduce the population tenfold. The chance for botulism with high dose shelf-stable irradiated foods will be the same as our current canned food supply, but without the intense heat processing, and also without the loss of a multitude of nutrients. The irradiated product will have an equivalent or better nutrient content than the canned food. We have been surviving just fine on canned foods and other foods -- canned food being a part of our food supply.

There has been talk about the destruction of nutritional value of foods. Irradiation does affect the nutritional value of foods, but so does cooking, freezing, drying, and other forms of processing. In some cases,

irradiation can make foods more palatable, more digestable, and can make nutrients more available than the natural food. The quality of available protein and PER -- which is protein equivalent ratio -- are essentially unchanged, even at high doses. Loss of vitamins is negligible at low doses, and comparable to thermal processing at high doses. The mineral content of irradiated foods is essentially unchanged.

The benefit of an extended food supply having good protein and mineral value, but a reduced yet available vitamin value, far outweighs the risk of preventing food irradiation processing based on a concern for decreased vitamin, or even nutritional content.

Emotionalism, scare tactics, and no substantive data to support adverse effects of food irradiation: Attached to my written statement is literature food irradiation opponents distribute to consumers. It shows that the issue of food irradiation is not their main concern, but is mixed with other issues relating--

ASSEMBLYMAN COLBURN: Excuse me, Dr. Fey. A couple of times you have referred to the emotionalism aspect. We are trying to get the facts here, and just leave out all the rest. The Committee can recognize, I think, what they would consider to be the public relations aspects. I am really looking for the pure informational part of it, if we could.

DR. FEY: Okay. Let's go on then. FDA responses to opponent allegations and concerns, which will have been aired again today, were answered adequately in the April 18, 1986 "Federal Register," and in a recent denial for stay of effective date of previously approved food irradiation regulations. Thus far, there has been no substantive data to support adverse effects of food irradiation at the current doses approved by the FDA and the USDA.

The ultimate experiment: I always think it is prudent to be conservative; to err on the side of safety. Perhaps the

only real way for us to know if there are any long-term undesirable effects of food irradiation, as the opposition points out, is to feed a large population irradiated foods for a few generations and monitor the major trends that develop. This is not only impractical, but unrealistic.

Safety, as defined by the FDA, means that there is a reasonable certainty in the minds of competent scientists that the substance -- meaning, in this case, irradiation -- is not harmful under the intended condition for use. It is impossible, in the present state of scientific knowledge, to establish with complete certainty the absolute harmlessness of any substance.

Looking at the benefits versus the risks of the technology of food irradiation, the price we can expect to pay if we ban the sale and distribution of irradiated foods in the State, as intended by these bills, and further delay commercialization of the technology, is unnecessary loss of life, continued unnecessary increases in food-borne illnesses resulting in adverse public health, and unnecessary increased costs to our State economy.

The risks, after 40 years of research demonstrating the safety of the technology, may amount to nothing more than a fear of the unknown, a reaction to emotion, or the insecurity of trusting our scientists and elected public officials.

The irradiation industry does have a track record using this technology for other beneficial means which should help to reduce fear of the unknown. According to Dr. Robert Cole, M.D., a radiation therapist, medical irradiation helps to save hundreds of thousands of cancer victims' lives each year in the U.S. Medical devices, sutures, syringes, and even cosmetics have been routinely irradiated to sterility over the past two decades, without any widespread adverse human incidents.

As mentioned previously, irradiation in foods offers the potential to save tens of thousands of lives, eliminates millions of food-related illnesses, improves public health, and extends our food supply.

The issue of the safety of food irradiation is perhaps best left up to competent scientists, such as those in our government and our State universities. I urge the Assembly Chairman, Dr. Harold L. Colburn, Jr., and the respected members of the Assembly Health and Human Resources Committee, to use the scientific resources available in deciding whether to proceed further with these bills.

I would like to conclude with a most recent perspective on food irradiation technology which was given by the Institute of Food Technologists, a United States professional organization with more than 30,000 member scientists, of which I am a professional member. They concluded: "Radiation processing of food is versatile, and has the potential to improve the preservation of foodstuffs, as well as their hygienic and other characteristics, and thus provide the consumer with more food of good taste, with freshlike quality and of wholesome, nutritious value." There is an attachment on that.

If we can't trust our country's independent experts, who can we trust? Please vote to defeat these bills.

ASSEMBLYMAN COLBURN: Thank you. I have two questions to ask you. How many different foods are being irradiated in the United States, which are either being sold here or outside of the country?

DR. FEY: Spices, herbs, and seasonings are being irradiated up to a level of 3 megarads, which is permitted by law in this country. I couldn't even begin to tell you what the volume of that irradiation is.

ASSEMBLYMAN COLBURN: I just want to get some idea of what is being irradiated now.

DR. FEY: There is also a large likelihood that products are being exported overseas to this country that have been irradiated.

ASSEMBLYMAN COLBURN: Do you mean that are coming here?

DR. FEY: Coming here that have already been irradiated. The National Bureau of Standards is currently working on an assay to try to determine whether a food has been irradiated, but, as was pointed out earlier, there is no way. There is nothing unique that comes out of irradiated foods that one can use to detect whether the food has been irradiated or not. They are working on an amino acid analysis, with a trace of amino acid, which may or may not prove to fruition. But, that is a problem right now. Foods are being irradiated overseas, and are being exported here. The foods are coming in cleaner because the microbiology is reduced on them. They are competing with the foods that are produced in this country, and, unfortunately, it is difficult for our people to compete in a situation where someone else is providing cleaner food.

ASSEMBLYMAN COLBURN: When you mentioned -- I think it was ethylene oxide, had been abandoned by some foreign countries--

DR. FEY: In Germany.

ASSEMBLYMAN COLBURN: In Germany?

DR. FEY: Yes, it has, as a carcinogen.

ASSEMBLYMAN COLBURN: Don't we use it for fruit, to kill--

DR. FEY: It is being used for a variety of reasons -- fruits, medical product sterilization. If the FDA were to ban ETO right now, there would not be enough radiation companies, and we couldn't build enough in the next five years, to handle the sterilization business that is out there. So, consequently, we are faced with another problem. We are consuming the carcinogens. We are consuming the residues of epichlorahydrine (phonetic spelling) and ethylene oxide in our

spices, herbs, and seasonings right now. The other alternative to that is irradiation, and it is a clean alternative, and there is a library of data to prove that.

ASSEMBLYMAN COLBURN: Is that what they are using in Germany in its place then?

DR. FEY: Yes, sir.

ASSEMBLYMAN COLBURN: They are using irradiation?

DR. FEY: Yes.

ASSEMBLYMAN COLBURN: Okay. I think that's all. Thanks a lot.

DR. FEY: You're welcome.

ASSEMBLYMAN COLBURN: Maybe we can take three people together; we have three chairs up here. From Food and Water, Inc., we have Lorna Salzman, Dr. Judith Johnsrud, and Dr. Walter Burnstein. You are all from the same organization. Would you like to come forward -- the three of you? Is this a combined statement? (negative response) No, okay. Well, whoever would like to lead off, and then if you could-- If there are things that are duplicative, I would appreciate your trying to condense your presentations.

L O R N A S A L Z M A N: Yes, thank you. We are actually covering different aspects of it. If there is anything that has been said by previous speakers, I will leave that out of my presentation.

ASSEMBLYMAN COLBURN: I would appreciate that, if you could.

MS. SALZMAN: Thank you for the opportunity to testify before you today. My name is Lorna Salzman, and I am Executive Director of Food and Water, Inc., a nonprofit public interest organization dedicated to research and education on food irradiation and other issues of radiation health and the environment.

You and your colleagues will shortly be asked to pass legislative judgment on an uncertain and potentially harmful

technology -- the irradiation of our food supply with gamma radiation. Ultimately, it is the American consumer whose acceptance or rejection of irradiated food will determine the economic success of this venture, as well as the stance of farmers, food processors, and food distributors and marketers.

While there are a number of factors that will influence their opinions, such as flavor, appearance, nutrition, and perceived wholesomeness, the factor of cost will loom large in everyone's mind. Failure to meet one or more of these tests will tell us quite soon what the outcome will be. But, prior to ultimate success or rejection, during the process of experimentation and marketing, American farmers and other groups in the agricultural sector stand to alienate consumers and endanger not only public health, but their own economic futures. Hasty, large-scale adoption of food irradiation, followed by consumer suspicion and resistance, could lead to the rejection of both irradiated foods, as well as non-irradiated ones that are merely suspected of being irradiated, foods of the same family as irradiated ones -- oranges versus grapefruit, for example -- foods from the same processor or distributor, or possibly even foods with a common geographic origin in a state or region. In this way, even growers, processors, and marketers of non-irradiated food could suffer from public rejection of irradiated foods, with some farmers facing the prospect of having an entire crop rejected. The economic consequences of this could be catastrophic.

Our research has convinced us that the agricultural community and many food retailers are being intentionally and seriously misled and misinformed by pro-irradiation interests, especially by the U.S. Department of Energy, about the costs, benefits, need for, and safety of food irradiation. We have concluded that the toxicological, radiological, nutritional, health, and economic risks of marketing of irradiated food, and of the facilities themselves, are being distorted or concealed

by irradiation proponents in their desire to foist this technology on an unwitting public and farming community, while, not incidentally, furthering the Department of Energy's intent on resolving the radioactive waste problem by dispersing it across the country.

As more accurate and complete information on these risks emerges, the connection between radioactive waste and our food supply will become clearer in the public's mind, something which can only lead to aversion and rejection, and serious economic ramifications. It would appear that the food industry is already anxious about this connection, for otherwise it would not object so strongly to clear, accurate labeling for irradiated food. Do you and your colleagues really believe that the linking of people's food with the image of radioactive wastes serves the best interests of the farming community and the food retailers?

In this panic market, unless absolutely 100% of our food supply is already irradiated, those who have played a role in it stand to lose, and lose badly. The American farming community cannot afford to let itself be manipulated into blindly accepting uncertain, untested technologies; it is already fighting for its life against ill-advised government and banking policies that have brought about foreclosures, bankruptcy, family disruption, heartache, even suicide. The very way of life for farmers is at stake, as they attempt to stave off loss of their land, livelihood, and traditions.

We cannot sit silently by while this new threat is added to the farmers' woes, for it is farmers who will be the chief ones to bear the cost of public rejection of irradiated food, not the giant food conglomerates, supermarkets, or irradiators. And, if the technology spreads, then the public will also pay, for the increased costs of irradiation that will eventually be passed on to them, a cost over and above the cost of all those other uncertainties of the global economic picture.

We share the empathy and concern for the farming community. It is for this reason that we wish to call your attention to some of the implications of food irradiation for the agricultural community.

1) Food irradiation does not eliminate the need for other preservation processes. Irradiation promoters suggest that both economic and energy costs will be reduced by irradiation. This is patently untrue. The International Association of Refrigerated Warehouses -- which is not anti-irradiation -- states that many products will require freezing prior to irradiation to reduce the changes in flavor and texture that irradiation produces. In addition, there are many natural enzymes in some foods that also require heat treatment.

Also, supplemental refrigeration will be needed after irradiation to prevent reinfestation or recontamination. Frank Peters, an expert in food irradiation who worked for the U.S. Army in the 1960s and recently testified before the Australian National Parliament, emphasized that irradiation was essentially useless at point of production or export, since foods could easily be recontaminated with bacteria or reinfested with insects or larvae after they had been exported abroad or after they arrived in their point of import, if the import area did not have the proper storage and refrigeration facilities. Irradiation of fish stored at refrigerator temperature deteriorates faster than non-irradiated fish, so it must be kept below freezing after irradiation, which, of course, makes irradiation superfluous, as Dr. Peters pointed out. Thus, the energy costs of this, plus the cost of transporting foods to the irradiator and of operating the facility itself, represent additional costs that will be passed back to the farmer, as well as on to the consumer.

This fact has a bearing on which foods will ultimately be irradiated. Irradiation is too expensive to use on cheap

foods that are marketed on a large scale, such as chicken, according to the European Parliament Committee on Environment, Public Health and Conservation. So, it will logically be targeted at high-price luxury foods like frogs' legs, shrimp, and tropical fruit, not at the mass-marketed food crops that are needed by the impoverished in the Third World.

2) Irradiation does not eliminate the use of pesticides, herbicides, and fungicides. Irradiation is proposed only for post-harvest fumigation to replace the now-banned ethylene dibromide. However, chemicals would still be needed prior to harvest to ward off insect and fungal infections. Noel Sommer of the University of California at Davis, says that food irradiation might actually require more fungicides, not less, because many plants lose their resistance to bacterial and fungal infections after they are irradiated. Moreover, in the magazine "HortScience," Sommer, an expert who has done 10 years of research on the issue, notes that irradiation makes fresh produce more susceptible to injuries suffered in handling and transport, due to peel damage and tissue softening, something also noted in a University of Florida review.

Thus, farmers and distributors stand to lose parts of their commodity shipments, which will, of course, be reflected in higher costs to them and to consumers. And, of course, attempts to market damaged or impaired fruit will stimulate consumer rejection that could persist indefinitely for certain produce.

In addition, shelf life is very often shortened, not lengthened, by irradiation, according to expert studies, due to the fact that the wound-healing capacity of crops like potatoes is lost through irradiation. Citrus fruits also demonstrate pitting and rind breakdown after irradiation. In any case, it is unclear why increased shelf life is considered beneficial, especially to small retail food markets which lack storage space and for whom quick turnover is an economic necessity.

3) Irradiation adversely affects the organoleptic qualities of fresh produce. While theoretical laboratory tests claim that pre- and post-irradiation refrigeration can minimize changes in the quality and appearance of fresh produce, this does not apply to food that has left post-irradiation storage and is on its way to the market. It is during this period that reinfestation, recontamination, and radiation-induced injuries, as well as injury from chilling itself, particularly with grapefruit, manifest themselves.

For example, irradiation speeded up the de-greening effect in lemons stored at 18 degrees C. for six days, but after this period, the de-greening rate was the same as that of non-irradiated foods, and some irradiated limes turned brown within two weeks, according to the University of Florida study, precisely the period when those lemons would be marketed to the public. On the other hand, irradiated oranges stored at 10 degrees C. for 20-35 days lost their orange color.

Thus, it seems that each individual commodity would require entirely different handling and storage, depending upon its post-irradiation response. If these were not nationally uniform, post-irradiation changes would occur, causing consumer rejection and causing the retailer, through no fault of his own, to lose all the so-called benefits of shelf-life extension.

4) Irradiation industry infrastructure must be developed from scratch. Because proven alternatives to food irradiation have been in use for decades, a technical infrastructure for irradiation would have to be started from the beginning, requiring entirely different kinds of skills, procedures, safety measures, and inspection, and technical and regulatory compliance. A nuclear technology is qualitatively different from a non-nuclear one, in that the source material is highly lethal, the consequences of human error, malfunction, or accident serious and irreversible, the impact on worker health irremediable, and the potential impact on the community and the environment socially unacceptable.

The lessons already learned regarding ineffective safety and inspection at nuclear facilities and the serious violations and disregard of safety measures already exhibited at the major New Jersey irradiators -- in one instance leading to loss of the Nuclear Regulatory Commission license after citation for willful repeated violations -- call into question both the will and ability of the irradiation industry to put public health and safety above its own interests.

What will be the results of such callous disregard if and when 1000 irradiation facilities, each with 10 million curies of cesium-137, are operating across the country? Can we trust the USDA or the FDA -- which was actually denied access to a New Jersey irradiator's premises and records for inspection purposes -- to enforce its regulations -- regulations that do not even exist yet for irradiation -- when it cannot even enforce those regarding non-irradiated foods? We note, for example, that food waxed prior to sale must be labeled as such under FDA regulations. When was the last time you saw an apple, cucumber, or turnip with a label indicating it was coated with wax, even though it clearly was? Can we seriously expect that each and every lemon, potato, or onion we buy from the bin will have the proper information on it? And, when the public learns that such inspection and enforcement do not exist or are haphazard and irregular at best, what will happen to the farming community when these millions of consumers turn away from improperly labeled products which they suspect of being irradiated simply because they cannot be sure of what they are buying?

We wish to point out that half of the two-year period imposed by FDA for requiring a printed notice of irradiation has already passed, and virtually no irradiated foods have been marketed in this country. Thus, when this labeling requirement expires next April, consumers will have no information whatsoever except for the vague deceptive radura, and will be

deprived of proper information and, therefore, a free choice in the market, that consumer right so highly touted by the food industry. If a particular irradiated food crop is marketed in one locale, consumers learning of this could well boycott that entire commodity nationwide, radura or not, fearing that all of that item had been irradiated. How do the farming community and the distributors feel about this possibility?

5) Costs of irradiation versus costs of present alternatives: As with all new technologies seeking financial and public support, the true costs to farmers and ultimately to consumers are unknown and, therefore, readily amenable to manipulation. The main hope of the irradiation industry lies in the purported economies of scale, whereby facility operating costs are postulated to decrease per unit of food treated as the quantities being treated increase.

The size of the irradiator is a big contributor to ultimate costs, which rise proportionate to size, thus necessitating an increase in volume. Here consumer acceptance or rejection is crucial. If $2 million is invested in constructing a facility, and consumers then refuse to purchase irradiated foods, the demand for further irradiation decreases, and the per unit cost of irradiation increases.

If the public then refuses to purchase irradiated foods, irradiators will then have to reduce their costs in some manner, thus leading to the cutting of corners in areas such as worker safety, hygiene, and radioactive waste disposal, all of which would compromise and endanger workers and the community.

Furthermore, year-round continual operation of this capital-intensive technology would be required for economies of operation, yet many items of produce are seasonal and do not conform to this requirement. Unforeseen or escalating costs could then lead to a demand for multi-purpose facilities that irradiate both foods and medical and pharmaceutical products. These present distinct problems, as noted by the ASEAN

Conference. It noted the following: loss of plant source efficiency in treating products of different densities and doses; difficulty in moving products to achieve the necessary wide range of dose levels; and the desire not to mix dirty foods with clean medical products. We might add that due to the need to continually adjust the dose in multi-purpose facilities, foods could be accidentally irradiated at higher doses than specified, from equipment miscalibration or human error. This over-irradiation could induce radioactivity in some foods.

Irradiation will target high-price luxury food. Those foods now being irradiated, with the exception of spices, are expensive seafood, like shrimp, frogs' legs, and papayas and mangoes, all of which carry premium prices and which are sought only by wealthy consumers. The ASEAN report explicitly says that radiation-processed foods may become commercially successful only under certain conditions, one of which is "attracting premium prices for products." They state then that "removal of the most important barriers -- appropriate legislation and radiation facility regulation -- is insufficient to guarantee commercial success."

Whether the public accepts or rejects irradiated food will depend upon the need, demonstration of wholesomeness, and retention of nutritional quality, as well as on the maintenance by the industry of low treatment costs and clear advantages over alternative treatments. Since public acceptance is far from guaranteed by government or the irradiation industry, it behooves the grower and small retailer to be doubly wary of the extravagant claims of the industry.

Vertically integrated food conglomerates can write off bad investments in expensive irradiation facilities; the facilities themselves can continue to do business with medical supplies. However, once the integrity and credibility of the primary food suppliers -- the American farmers -- have been

damaged, there will be irreversible penalties and costs that this sector alone will have to bear. What will happen if farmers using transportable irradiators, which could have accidents anywhere and which are notoriously defective because of their mobility, have accidents on their farms? Have American farmers been informed of this kind of possible liability or the myriad other ones that could occur anywhere in the food production and distribution system that would cost them their reputation and livelihood? Can the farming community afford to become part of this risky venture? Should our lawmakers and elected officials allow them to be led on?

The State of Washington, a major agricultural region seeking to expand its export markets into Asia, sponsored a feasibility study for its fruits and vegetables. They asked many questions regarding the potential success of irradiation, the first of which was: "Can irradiation processing command premium prices for products?" This question alone indicates that the arguments about feeding the world's hungry, improving nutrition, and reducing storage losses are totally without merit.

This report raises economic doubts, too, because it states that it is premature to build a privately financed irradiator in the state, due to uncertainties about consumer demand, and urges a co-venture between government and private industry prior to full commercialization; in other words, saddle the U.S. taxpayer with the ultimate costs of failure by obtaining government subsidies for this untested technology -- precisely what the U.S. Department of Energy is doing right now in setting up partnerships with state agricultural departments to build irradiation facilities, providing cheap cesium-137 and, in one case -- Florida -- providing it free, as well as millions of dollars for facility construction.

We cannot fail to note here the parallel with development of the nuclear power industry, which required

extensive government subsidy before private industry was willing to move ahead -- subsidy which did not prevent the subsequent imposition of huge unforeseen costs of nuclear accidents, waste disposal, accident liability, and more, on the public at large, not on the utility or reactor manufacturer. And, like the nuclear power industry, these unpredicted, unknowable costs are more likely to occur in highly complex technologies and facilities such as irradiators, where the environmental, health, and economic consequences of failure and accident are far more severe than at non-nuclear facilities.

Since, by admission, the United States irradiation industry seeks to enlarge its export markets, legal, regulatory, and institutional barriers in other countries could also impede the technology, as well as raise its costs for both foreign and domestic consumers. Some countries ban irradiated food outright for health reasons; some ban it to protect their own food sectors, such as Japan does. However, recent developments abroad suggest that overcoming these barriers may be difficult. The European Parliament recently reversed its authorization for food irradiation, and is recommending a ban and more studies to find additional alternatives to irradiation for processing, preserving, and hygiene. The British Medical Association also reversed its original approval and a new Canadian Parliament Committee also has come out for a ban.

In light of these actions, it is clear that the United States agricultural sector cannot assume that foreign markets and demand will increase. For American farmers to put their reputation, produce, and livelihood at risk by associating food with the irradiation industry and radioactive wastes before there is a clear consumer acceptance, demonstrated need, and demand, as well as proof of its benefits and safety, is both foolish and foolhardy. Legislators having the farmers' best interests at heart would better serve this constituency by pointing out the economic pitfalls that await those who embrace this untested technology.

ASSEMBLYMAN COLBURN: Thank you. I would like to comment that what you said was very instructive to me, as has been this whole hearing, but I did find in it a mixture of things that were both relevant and not too relevant to the bills. You know, there was that business about educating the farmers, the public, and all that. I appreciate that, but as we consider the bills, we are going to have to try to carve this out and put it together with respect to our bills.

MS. SALZMAN: Well, there is a considerable farming sector in the State of New Jersey and, of course, what happens here I think will have national ramifications.

ASSEMBLYMAN COLBURN: Well, I know, but that information ought to be communicated to them.

MS. SALZMAN: Well, we certainly intend to do so.

ASSEMBLYMAN COLBURN: Next, and please tell me your name.

D R. J U D I T H H. J O H N S R U D: Mr. Chairman, my name is Judith Johnsrud. I am the Research Director for the nonprofit organization Food and Water, Inc., which is chartered here in the State of New Jersey. I hold a doctoral degree in the field of Geography from the Pennsylvania State University, and have specialized in the field of the geography of nuclear energy, radiation pathways in the environment, and the interrelationships of the entire nuclear fuel system for a good 20 years. I am a member of the Pennsylvania Department of Environmental Resources' Public Advisory Committee on Low-Level Radioactive Waste. There are, in fact, some relationships here and I think you, as a sister state facing the issue of waste management from those wastes which are considered low level by definition here in the State of New Jersey, perhaps can share the insights we are looking at in Pennsylvania on this piece of the issue.

We very much appreciate this opportunity to express our views on Assembly Bill 3150, and I appreciate the opportunity to speak to you today.

We have prepared for Assemblyman Kelly, at his request, a detailed reserach document -- a review of various irradiation issues, entitled "A Commentary on the Technology of Processing and Preserving Foods by Exposure to Ionizing Radiation." I commend this document to you.

ASSEMBLYMAN COLBURN: Excuse me. Is it recent, because he gave me a packet about two inches thick that I read some months ago?

DR. JOHNSRUD: It was dated March 20. I think we actually presented it around the beginning of May.

ASSEMBLYMAN COLBURN: I don't remember that one, okay. I read everything I received.

DR. JOHNSRUD: We hope it will be of some assistance to you in this deliberation.

Despite the length of time that food irradiation technology has been available, important health and safety aspects of food irradiation remain unresolved, in terms of both food safety and the role of this process within the nuclear fuel cycle. Of key significance in assessing the advisability of food irradiation are: First, the overall societal impacts, population-wide, of the widespread utilization of this technology. But secondly, and probably equally important, are the questions of choice for each individual consumer. Therefore, we conclude that these issues are, indeed, matters of public policy that transcend the narrow food industry bounds and their concerns for the creation of, for them, a profitable industry. These are clearly matters of public concern. We especially commend this legislative body for having exerted timely leadership in examining these questions.

In my view, there are at least five major issues which should be addressed by the Legislature prior to any acceptance of the commercialization of food irradiation, and I will try to summarize these so as not to overstress the parameters of the Committee's patience.

ASSEMBLYMAN COLBURN: We will be studying it all later. You know, this is a first exposure.

DR. JOHNSRUD: Yes, I assume so. Issue one is the question of food safety and health effects. You have heard from several experts from both sides of this issue. Really, the question for the public is, is irradiated food safe to eat? The answer to this crucial question for the total population over time consuming irradiated food as a substantial portion of their diet is that no one really knows. I think you have heard the two sides -- the multiple sides of the issue. Some studies indicate vitamin content appears to be diminished. Some studies show no discernible damage. Some studies show possible detrimental effects from consuming a diet that contains freshly irradiated foods.

When we have a mixture of scientific research results, in terms of public policy it would appear that there is particular need for caution prior to proceeding with the massive utilization of the technology.

Most importantly, then, definitive large-scale, long-term studies of humans and animals which are adequate to determine whether or not there are adverse effects on human health from the lifetime consumption of irradiated foods as a significant portion of the total dietary intake, had not, to our knowledge, been completed and evaluated prior to the FDA approval. And, indeed, as you have heard, FDA issued its final rule permitting the irradiation of fresh fruits and vegetables, pork, and other foods, despite these mixed findings on the part of research scientists.

Now, food safety is clearly a premier concern for all of us. Food is essential to life, and we are all consumers. The history of our commercial food industry in this country is replete with examples of additives and treatments which were shown after the fact of regulatory approvals to be detrimental or, indeed, truly hazardous to human health. In the case of

food irradiation, FDA has chosen, contrary to its customary practice, to grant its approval for irradiation of whole foods up to 100,000 rads, without requiring any long-term animal feeding studies to determine safety. The agency has also chosen to assume that radiolytic products induced in foods by exposure to ionizing radiation will be in sufficiently small concentrations to cause no significant human health damage, and yet we have really no clear definition of what constitutes a sufficiently small concentration. We are well-acquainted and work within the context of parts per million and parts per billion of toxic substances in our foods and in our environment. amd recognize that, indeed, very small concentrations may constitute a significant long-term damage not immediately observable to human health.

As you have heard from Dr. Louria, the five studies upon which FDA appears to have relied raise a number of questions concerning their adequacies. An example of the questionable nature of these scientific studies was the Chinese study of medical students, which the proponents have used to substantiate their claims of no observable effects. I was particularly puzzled at the use of such a study as a demonstration of safety and non-effect, given the shortness of the study time. Seven to fifteen weeks is the statement given in the study for only 400 to 500 -- about 450 -- subjects.

Now, this simply does not, in our view, constitute adequate approach to research in order to test the long-term effects. Furthermore, to the best of our knowledge, no requirements exist for the testing of centergistic effects of post-harvest irradiation of foods and the pre-harvest pesticide residues that may remain upon the foods. This certainly seems to be an area requiring much greater investigation than we have seen in the literature.

Our conclusion: The jury is still out with respect to the long-term safety of consuming substantial quantities of

irradiated foods. Therefore, the use of ionizing radiation for whole food preservation, or for disinfestation, bacterial control, or control of ripening time, constitutes, in blunt terms, a society-wide form of experimentation with our nation's food supply and with public health. The burden of proof of safety has thereby been lifted from the proponents of food irradiation and shifted improperly, in our view, to consumers. In our opinion, the lack of definitive scientific showings of safety, the sweeping assumptions underlying the FDA final rule, and the body of research that identifies negative effects together force the conclusion that safety has not been proven and, therefore, in the absence of any overwhelming societal need for this technology, wise public policy would be to require completion of the basic scientific research prior to commercialization of food irradiation.

The second area of concern that you, as a legislative body, would wish to consider, I should think would be that of the actual safety of individual facilities and of the transportation of radioactive materials utilized by the food irradiation industry. We anticipate that although cobalt-60, with its half life of five years and hazardous life 10 or 20 times that duration -- namely 50 to 100 years-- We anticipate that cobalt-60 currently used for irradiation of equipment, will probably be replaced by the use of cesium-137. Cesium-137 is an especially biologically hazardous radioisotope. It has a 30-year half life and, therefore, its hazardous life -- the time period in which it must be sequestered from the environment and from the biosystem -- is 300 to 600 years. Nevertheless, the Nuclear Regulatory Commission considers cesium-137 to be a short-lived isotope. Each food irradiation plant is projected to contain many thousands to several millions of curies of the radioactive source material, most probably cesium, during production and transportation. Therefore, it is going to be necessary to look at that entire

system of production utilization and disposal in evaluating the desirability of moving ahead with food irradiation in New Jersey.

Commercial irradiation facilities are licensed and regulated by the NRC. Its record of nuclear reactor regulation has been repeatedly criticized by (indiscerbible). NRC's design and operational standards for commercial irradiation utilization facilities are, to the best of my knowledge, less stringent than those applicable to nuclear reactors. Agreement states -- those states that have an arrangement with the Nuclear Regulatory Commission to be responsible for licensing and regulation of certain nuclear facilities -- may have the responsibility for regulation of these facilities, but they are subject to the overriding regulatory authority of the NRC. I will speak more about that in a moment.

Thus, even if accidents are avoided, and we certainly do have a record of unfortunate accidents throughout the history of the equipment irradiating industries in New Jersey, nevertheless, there is another entire realm of concern about the potential pathways of radioactive releases to the environment. These occur with respect to the permissible emissions from facilities considered to be standard -- or rather routine -- normal emissions from the plants.

The standards for radiation exposure for members of the public, as well as for workers in the nuclear industry, have been undergoing a major revision over the past several years. In January of this year, EPA published its comparable revised worker exposure guidelines, which will be utilized by the Nuclear Regulatory Commission. The Department of Energy had already approved its revised standards two years ago, and the NRC is in the latter stages of doing so currently. These standards markedly alter the permissible doses to workers and to the public and, in many instances, increase the overall doses that are permitted to workers in the industry and to the public.

These new standards are based upon international recommendations that were developed 10 years ago, and they fail to take into account the significant recent findings about human health and radiation.

Recent research shows that exposures of workers at or below the older permissible levels have been associated with increased incidents of certain cancers. New research from Britain within the past six months, strongly suggests that childhood cancer and leukemia deaths are positively related to early embryonic exposures to background terrestrial gamma radiation. This study was conducted in the British Isles by a distinguished epidemiologist, Dr. Alice Steward (phonetic spelling), and her colleague, Dr. George Neil (phonetic spelling). The study was based upon data -- detailed data -- of background radiation levels within Britain fairly recently released, and upon data concerning childhood cancers and leukemias, which Dr. Steward has been collecting in the Oxford Survey of Childhood Cancers and Leukemias for 35 years.

In the past, children born pre-cancerous or pre-leukemic, and having weakened immunological systems, might have succumbed to the infectious diseases of childhood. Indeed, when Dr. Steward began her work, that was the case. But, during the late 1950s and early 1960s, as we developed the antibiotics and the vaccines to help those children to survive measles and pneumonia and so forth, such children now are far more likely to survive long enough for incipient cancers and leukemias to develop, following the expiration of the latency period. Cancers are now identified among the leading causes of death of children.

This information, I think, is of importance to any community and to any state -- and to the nation -- considering expanding the availability of radioactive materials in commerce and the potential for release of additional radioactive materials from such enterprises into the environment.

Other research has recently revealed that data on radiation exposure and effects from Hiroshima and Nagasaki may have been improperly interpreted in developing our radiation standards. In other words, we, I think, can anticipate that within the near future we are going to have to look very carefully again at the levels of radioactivity that are permitted to individuals in our society from commercial uses of atomic energy in its many manifestations. The NRC currently permits an individual to be exposed annually to approximately five times our naturally occurring radiation levels, in addition, of course, to the background radiation exposures we all receive, and in addition to medical exposures. Workers are allowed to receive annual doses 50 times greater than naturally occurring backgrounds that we experience in this part of the country. Some experts have been urging, for nearly a decade, that, in fact, radiation exposure standards should be made more, not less, stringent.

I think I will by-pass the discussion that follows in my written statement on the facilities here in New Jersey. You have information on the records of the radiation facilities that have operated in this State. I would observe that the unexpected low probability event does happen. An irradiating facility in our State of Pennsylvania -- two years ago -- was in the direct path of a tornado, which certain is a very low probability event, and one against which such plants are not hardened, or protected. It did considerable damage to the facility itself. We are told that the radiation source -- cobalt-60 -- was sufficiently protected at a below-ground level, and we are happy for that.

But, it is important to note that the Nuclear Regulatory Commission does not require, and will not permit, consideration of sabotage or terrorist damage in the course of licensing production and utilization facilities. Such events are ruled beyond the scope of the proceedings, and are never

subjected to scrutiny in an adjudicatory hearing. I would note that within the past week, we have seen publication of an Iranian threat to sabotage U.S. nuclear facilities. I think we do have to consider that the quantity of cesium-137 that would be stored and utilized within each individual radiation facility, is going to be substantially larger than the total quantity of cesium-137 estimated to have been released in the course of the Chernobyl accident last year. This, in turn, as you may have noted in the literature-- This release at Chernobyl is expected to be responsible for many latent cancers and premature deaths over the period of the coming several generations, given that half life of 30 years, and hazardous life of 300 to 600 years, as the cesium material incorporates into the food chain and spreads, then, its risks among many hundreds of thousands of millions of people. The estimates of premature deaths vary from a few thousand to many tens of thousands and more.

It is, therefore, we would say, prudent to conclude that facilities of this nature cannot be depended upon to be safe neighbors. We have touched upon the issue of transportation of these radioactive materials and, indeed, there is a history of accidents involving cobalt-60 sources on our interstate highways, and in our communities.

Now, to move to the third and fourth of the major issues, these relate to the role of cesium-137 as a food irradiation source material, in connection with the nuclear fuel cycle and, most specifically, radioactive waste management. As you know, the Department of Energy, under the Nuclear Waste Policy Act, is responsible for the disposal of high-level radioactive waste in deep geologic repositories. It is also charged by Congress to proceed with programs that will store such waste temporarily in monitored retrievable storage facilities, and reduce thereby, they hope, the burden of radioactive wastes by such uses as recycling of some highly active materials for commercial purposes.

The Federal laws, principally the Low-Level Radioactive Waste Policy Act of 1980, and its 1985 amendments, require each state to become responsible for the mangement and disposal of the wastes that are legally defined as low level, although they may not be low in activity -- wastes which are generated by commercial activities within each state.

The Department of Energy has thus far been unable to gain siting approval for a high-level waste facility either in the western states -- where it is looking for its first repository -- or in the eastern states. New Jersey, I assume you are aware, was among the 17 states that DOE had under consideration for its second high-level waste repository. You didn't survive the first cut; neither did Pennsylvania, and it was left to the good folk of New England to have to deal with this impending development of both the first and second high-level radioactive waste repositories. It is a matter that we have to get on with, unquestionably, having created the wastes. But, DOE is having a great deal of difficulty, and has recently warned the Congress that it will be unable to put into operation a high-level waste facility by the legal deadline of 1998. It is suggesting perhaps the year 2003 as the earliest available date for an operating facility. That is if the 40 pending lawsuits can be resolved sufficiently for DOE to move forward.

This coming week, the Department of Energy will be introducing authorizing legislation, however, for a monitored retrievable storage facility for the storage of radioactive spent fuel from the nation's commercial reactors. DOE spokesmen recently, in congressional hearings, and the Director of the Office of Civilian Waste Management speaking to me directly in response to my question, have stated that that agency has no objection to the revival of the commercial technology of reprocessing spent fuel. This is a procedure which was abandoned in the 1970s due to its environmental

hazards, its costs, and nuclear weapons proliferation concerns. DOE officials are now citing, as the major benefit of a revived reprocessing, the recovery of cesium-137 for food irradiation. In addition, of course, plutonium, which then could be made suitable for future nuclear weapons through the use of laser isotopic separation, would also be recovered during reprocessing, and presumably would be stored for some future use.

These public positions of the DOE Secretary and the head of waste management are consonant with the DOE By-Product Utilization Program, a major purpose of which is to demonstrate the efficacy of food irradiation. Cesium-137, according to DOE's documents, comprises approximately 55% of the radioactivity in the already reprocessed military high-level waste that DOE currently is holding in storage. Recycled to become the source material for food irradiation, this extremely hazardous cesium waste would then be put into use at multiple sites, transported on highways, and would result in additional quantities of contaminated materials that must be treated ultimately as radioactive waste.

These wastes, you are aware -- radioactive wastes -- cannot be chemically neutralized or destroyed by burning. They remain hazardous until they have physically decayed away to extremely low concentrations, and, therefore, must be sequestered from the biosystem for their full hazardous lives.

Now, in addition, the Nuclear Regulatory Commission is proposing to redefine high-level radioactive waste in a way that could exclude cesium-137 wastes associated with irradiation industries from the Federal high-level waste geologic repositories. DOE's redefinition of high-level waste would require that in order to be eligible for permanent geologic disposal, a solid radioactive waste must contain both short-lived and long-lived radioisotopes in concentrations above NRC's arbitrary limits. For cesium-137, that limit is

4600 curies per cubic meter. Thus, mixed with other solid material to reduce the radioactive concentrations, these cesium wastes from commercial facilities, for food irradiation presumably, apparently could become the responsibility of the states, not the Department of Energy.

Now, I don't know whether the State of New Jersey has looked carefully at this aspect of DOE's proposal. I know that we found that our State of Pennsylvania had not. I would suggest to you that this is a matter of very substantial concern, since, in your two-state Northeast Regional Compact, either you or Connecticut presumably will become the regional repository for wastes. It also appears that there is substantial interest on the part of the industry in altering the impediments on the importation of waste from out of region, thus there will become, presumably, some commercial competitiveness involved. I would suggest to you that this is a matter that you may want to look into to in substantial detail in the near future, since the comment period on NRC's proposal for high-level waste expires on June 29.

There is one other aspect of low-level waste that I do want to bring to your attention. That is the proposal by the Nuclear Regulatory Commission to deregulate, at the bottom end, the very low activity wastes from various nuclear facilities; the so-called below-regulatory concern approach of the NRC, whereby wastes are compared with other sources of radioactivity to which the public is exposed, and then are declared to be de minimis, very low activity -- trivial is the terminology used by the agency. These wastes, then, would be permitted to be released into the environment, without concern for their radioactivity, either in landfills, waste-to-energy incinerators, or down the drains and into the sewerage systems.

The concern here clearly would be that at any one such collecting point, multiple sources of the below-regulatory concern wastes, deregulated, could come together, and there

would be no way of identifying the nature of those wastes. They are not required to be labeled, monitored, or otherwise controlled.

Secondly, there is the question with respect to what you would call the cumulative overall impact in the environment of increasing multiple sources of routine emissions -- normal emissions, occasional accidental emissions -- that have the effect of sickening the radiation environment about us. If, indeed, Dr. Stewart's research in Britain is proven to be accurate, this, I think, says to us that we must exercise substantially greater care with respect to these activities than has been the case in the past.

At the base of our wrestling with these issues, I believe, lies the fact that the governing Federal law -- the Atomic Energy Act of 1954, as amended -- has in its statement of our national purpose with respect to nuclear energy, a mandate for the maximal development, commercially and militarily, of the uses of the atom. That was the time perhaps of optimism with respect to atomic energy. But nowhere in that statement of national policy is there any reference whatsoever to the protection of the public health and safety. Many of us feel, therefore, that given the preemption over radiological safety and radiation protection standards, which has accrued to the Federal government under the Supreme Court decision in a Minnesota case in 1970, that the states have been placed in a very difficult position with respect to regulating radioactive materials and activities, and exercises their responsibilities for the well-being of their citizens. They are given-- The states are given responsibilities, but they are not given the full authority to do the job.

I thank you very much for your patience, and I hope we can continue to be of assistance to you.

ASSEMBLYMAN COLBURN: Thank you. I think you answered one question I had, which was: How much material is in one

plant? You know, is it a large-- I don't know the sizes. With Chernobyl, I think you said the amount of cesium that was released was about equal to what is present in a plant.

DR. JOHNSRUD: It is less than we would anticipate in one of these facilities. The estimate I have seen-- I can't believe it is a very accurate estimate, because, of course, it was an explosive.

ASSEMBLYMAN COLBURN: Yeah, I don't know how you figure out what the Russians tell you.

DR. JOHNSRUD: Yeah, who knows? Who was counting? But, I have seen an estimate of 100 million curies of release, of which only about 1%, as I understand it, was estimated to be cesium. Now that would be approximately one million curies. In the case of the Three Mile Island accident, we had a release of something on the order of 10 to 13 million curies of xenon and a certain amount of iodine and some other isotopes. But the Chernobyl accident, of course, was magnitudes of release greater. I think it does help us, perhaps, to put into context the potential for environmental hazard in the event that something goes very seriously wrong. Thus far, we have only had apparently relatively minor leaks and releases from such facilities. We would hope that the regulatory capability of the state, or of the Federal government, would be sufficient to ensure that there would never be larger. But, unfortunately, the nature of accidents is that they consist of things that you don't expect to have happen.

I find myself very concerned that the NRC consistently, through its licensing history, has never been willing to address serious accidents at any of its facilities -- reactors -- or at other facilities. The worst case accidents are considered to be low probability events, and we cross our fingers and hope that low probability events will not happen, but they do.

ASSEMBLYMAN COLBURN: Okay, thanks a lot. Yes, sir? (in response to gentleman in the audience)

D R. W A L T E R B U R N S T E I N: Mr. Chairman, may I make a request? I am not sure. We have a scientist here who has done a lot of investigation into the studies of this over the past 20 years. I am not sure he is going to be able to stay. His name is Dr. Piccioni. I can stay all afternoon. May we have Dr. Piccioni speak now?

ASSEMBLYMAN COLBURN: Yes, if he has to-- Do you have a time problem, Doctor?

D R. R I C H A R D P I C C I O N I: I can stay, it turns out.

ASSEMBLYMAN COLBURN: Okay.

DR. BURNSTEIN: I am Dr. Walter Burnstein, President of Food and Water.

ASSEMBLYMAN COLBURN: What type of a doctor are you?

DR. BURNSTEIN: I am a general practitioner in Dover, New Jersey.

ASSEMBLYMAN COLBURN: Okay.

DR. BURNSTEIN: What I would like to do with my talk-- It will be short. I would just like to summarize, and put into perspective what we have heard up to now, and what we have been hearing for the past year or two on food irradiation.

In the "New England Journal of Medicine," May 8, 1986, an article entitled "Progress Against Cancer?" by John Bailar of the Harvard School of Public Health and Elaine Smith of the University of Iowa Medical Center--

ASSEMBLYMAN COLBURN: I know what you are going to tell us.

DR. BURNSTEIN: They concluded--

ASSEMBLYMAN COLBURN: Go ahead.

DR. BURNSTEIN: Well, you read the medical literature. They concluded--

ASSEMBLYMAN COLBURN: I read it, but the rest of them didn't, so it's all right.

DR. BURNSTEIN: Well, that is where I think this is put into perspective. I will get through this very rapidly.

ASSEMBLYMAN COLBURN: That's okay.

DR. BURNSTEIN: They concluded, in assessing the overall progress against cancer during the years 1950-1982, "We are losing the war against cancer." They claimed, in their abstract, that a shift in research emphasis, from research on treatment to research on prevention, seems necessary if substantial progress against cancer is to be forthcoming.

ASSEMBLYMAN COLBURN: It sounds like public health people, though, doesn't it?

DR. BURNSTEIN: Yes, they are. They are both public health.

ASSEMBLYMAN COLBURN: You know, there was an exchange that followed, to some extent, so it's true. I kind of hated to see that get out, because, boy, I'll tell you, it takes all of our hope away. But, anyhow-- I know, I read that.

DR. BURNSTEIN: It is very controversial. Then, in an article in The New York Times, April 16, 1987, the headline of the article is, "Gains Against Cancer Since 1950 Are Overstated." In the beginning of the article, the first paragraph reads: "Gains in treating cancer in the last three decades have been small and overstated by Federal health officials, according to a detailed analysis completed by a congressional investigative agency. For the majority of the 12 most common tumors, there was little or no improvement from 1950 to 1982 in the rate at which patients survived the disease, the agency -- the General Accounting Office of the United States Government -- concluded in a 131-page report to Congress." The General Accounting Office released this study in April of 1987, which again shows that treatment of cancer leaves a lot to be desired at this time, and that the critical way to think about cancer in our society -- according to both of these articles -- is to think about prevention.

When we think about prevention, we have to change our priorities regarding what is important to us and what should be done technologically. This is in line with what Dr. Louria's research has been doing in the past few years on technology and the uses of technology, and the public health effects of technology in our society from a medical and epidemiological standpoint. What kind of technology can be used safely, without increasing the burden on us, the people of this country, and on all future generations? Essentially, what we are saying is, at this time, when we are aware of the burden that our population carries due to environmental problems that we have created ourselves in our society, the burden on our health, the burden on our lives, the burden on all future generations, we should not be increasing the environmental burden, we should be lessening it.

In my own experience -- and you might be able to relate to this-- I don't know what is happening in South Jersey as a physician, but in my own experience -- and this is definitely not a sophisticated study; it is my own observations -- when I was a young man in Brooklyn, there was very little cancer at the time compared to the amount of cancer in our society now. Therefore, cancer was not part of my experience growing up. Cancer was not common in my neighborhood; it was not known in my family, or among my acquaintances. I was unaware of the existence of cancer, and it was not unusual at that time for people to be unaware of cancer. Today, my two teen-age children both have friends who have cancer, and that is the experience of many teen-aged people. The major disease death of children up to the age of 14 in our society today is cancer. That is the burden, that is the heritage we are leaving our children.

When I started practicing in my local hospital in Dover, New Jersey 25 years ago, there were very few cases of cancer in the hospital. We physicians would tell each other to

go and see the case of cancer that was on the third or fourth floor, so that we could become acquainted with the disease, its diagnosis, and its treatment. We took care of our own cancer patients. Today, a short 25 years later, we have full-floor cancer wards in our hospitals that are overflowing with patients. We have full-time oncologists, a specialty that did not exist in our area 25 years ago. We have full-time nurse oncologists. Cancer has become a very big business because of the increasing number of cancer patients. One of the reasons for this increase in cancer, again, is environmental problems and environmental pollution.

The American Cancer Society states that between 70% and 80% -- and that was their figure three years ago when I called them -- of all cancers are environmentally caused. To relate this to food irradiation-- You have heard the studies that have been reviewed here today by the scientists -- the independent scientists who spoke today. When we called the FDA to discuss the fact that they admit there will be toxic chemicals in the food due to irradiation, the answer of the scientist who we spoke to at the FDA was, "Yes, we agree. There will be toxic properties in the food. They may be cancer producing, but don't worry about it. The toxic properties will be in such small amounts that there is nothing to worry about."

We feel this is the reason for the large increase in degenerative diseases today, such as cancer. These toxic materials are small in each individual area, but when we drink the water, eat the food, and breathe the air, these toxic chemicals are magnified in our own bodies; in our livers, our spleens, our lungs, our blood, etc. And this is the reason we have such a large increase in the amount of cancer, as well as other degenerative diseases. These small amounts become magnified and, therefore, we have to prevent these small amounts from occurring whenever possible.

We who are opposed to food irradiation are not asking for any special dispensation. We ask only that clear evidence of safety be demonstrated before our children and grandchildren are forced to consume these foods over the course of their entire lives. We who are opposed to food irradiation are not swayed by irrational emotion -- as you have been told today -- but are driven by well-guided passion. We are passionate for life. Not only do we wish to protect those who are living, not only do we wish to protect the fetuses still unborn, but we wish to ensure that those who are yet to be conceived will be born to normal and healthy lives.

As you know, we, your constituents, reflect a broad diversity of opinion. It is both the honor and challenge of our duly elected officials to represent and protect these many interests, for it is that very diversity -- the freedom to think one's own thoughts -- that makes America great.

Therefore, we, the people, have many different philosophies about what our elected representatives should do in order to represent us. We have different ideas and philosophies about the economy. We have different ideas and philosophies about education. We have different ideas and philosophies about foreign and national policies. But, there is one point which almost everyone agrees upon, and that point is every citizen's right to be protected against violence. Let us be clear: Food irradiation, lacking definitive evidence of safety, is violence. It is violence against your constituency; it is violence against the environment; and it is violence against future generations.

Let me remind you that there are forms of violence other than the blatant and overt. Just as psychological abuse is now considered by experts to be as insidious and destructive as overt physical abuse, so we must recognize that there are forms of invisible violence -- attacks against our bodies, our cells, and our futures -- which, in the long run, may produce

more harm than the visible violence against which we can defend. Included among these invisible forms of violence are the many hazards posed by food irradiation: the destruction of essential vitamins and minerals; the introduction of new chemicals and unique radiolytic products to the human diet, without adequate testing for safety; the contamination of our water, air, and soil from radiation leaks and from the illegal disposal of radioactive wastes, events which have occurred on three occasions at Morris County based irradiation facilities -- it is not fantasy, they have occurred; the vastly increased need for the transportation of radioactive materials on highways, the corresponding increase in the potential for accidents, and the increase in the amount of radioactive materials requiring ultimate isolation; the creation of an environment wherein the illegal sale of tainted, spoiled, or low-quality foods to the public becomes possible, as has already happened in Great Britain; and, the elimination of America's freedom of choice in the marketplace by depriving consumers of full and accurate information.

These many aspects of food irradiation are forms of invisible violence. They violate the human cell; they violate genetic material; they violate the environment; and, they violate the potential well-being of future generations. For these reasons we, your constituents -- the many thousands of local citizens who have voiced our opposition to food irradiation -- demand that you, our representatives, act now to protect us from this violence.

At times, government actions represent inferior thinking. Certain government decisions, such as the decision of the FDA to promote and to allow food irradiation, are decisions that are against our own self-interest. It is an example of inferior thinking by the government that is supposed to be protecting us, but is not. But, at other times, our government represents the very best, the most capable thinking

and compassion that can be found. We are asking you, our elected representatives, to rise to this occasion, to represent the very best thinking, to take into consideration the science, the true data about the inability to prove that this technology is safe. We are asking you, by your decision, to protect us by releasing A-3150 for a vote, and by you, yourselves, supporting and cosponsoring Assemblyman Kelly's bill. We are asking you to show that you are concerned about yourselves, your children, your grandchildren, and all of society, and to show that the people of this country can be proud of the actions of this Health and Human Resources Committee of the State Assembly, as we are now proud of the main Legislature for passing the New Jersey bill prior to New Jersey passing its own bill.

Thank you. (applause)

ASSEMBLYMAN COLBURN: Okay, thanks a lot. Kathleen Boucolo, would you like to step into the target area -- from the Department of Commerce? I don't know whether Kathleen has survived this long, or-- (Ms. Boucolo not present) Well, we will call her later. Is George Giddings still here? (affirmative response) Come on up and step into the eye of the hurricane.

We are getting to that point in the hearing where if people could summarize what they had to say, it would help us all. I don't know what the temperature is outside. It is probably getting close to 97. We might be radiolyticed, or something.

D R. G E O R G E G. G I D D I N G S: Well, I won't promise to push the applause meter as high as the previous group.

ASSEMBLYMAN COLBURN: I know you won't, but as long as there aren't too many boos and cat calls, it's all right. Please give Dr. Giddings your attention. I know you will be as courteous to him as you have been to others.

DR. GIDDINGS: Well, to start with, I am a Ph.D. graduate of Michigan State University in Food Science and Human Nutrition, with a minor in Biochemistry. I began my professional career after receiving a bachelor's degree in 1963 with the U.S. National Food Irradiation Program, which was then based at the U.S. Army Research and Development Center in Natick, Massachusetts, outside of Boston.

I have been involved in food irradiation research and development as a graduate student and as a faculty member in Food Science at two major universities, in the Federal government research program, in international development in Latin America and, most recently, in the radiation processing industry -- the gamma processing industry.

On returning with my family from Latin America in 1981-- At that time the Food and Drug Administration was just publishing an advance notice of rule-making on the approval of certain irradiated food applications, so I thought it would be an appropriate time to enter the industrial side of this activity, having had the governmental and academic, and that brought me to New Jersey, where the irradiation processing industry is by and large centered.

With that by way of background, and in the interest of time, I am going to be brief. I would just draw your attention, if I may, to the abstract on the cover page of the written testimony. What I have tried to do in the written testimony is put aside the peripheral inflammatory rhetoric and alarmist obfuscation that I have been countering over the past months and years -- as you perhaps well know if you have been watching your mail lately -- to put all of that aside and try to focus narrowly on the nature of the two bills under consideration. What I have done in the abstract, with a lot of elaboration in the body of the testimony, is to suggest that the proposed amendment to Chapter 5, point 8 of the State Food and Drug Act -- Title 24, namely-- If it is to be amended, I

submit that the only rational, responsible, prudent, and effective manner of doing so is in such a way as to preserve the complete harmony and consistency that presently exists between Title 24 and this chapter specifically, which deals with the definitions of adulteration, and the Federal Food, Drug and Cosmetic Act, specifically section 402, which does likewise. If you compare the two sections of the two acts -- the State and Federal acts -- it is very clear that there is deliberate, complete consistency and harmony between the two in defining foods as being adulterated.

The only departure is the Federal Food, Drug and Cosmetic Act, namely section 402, has seven clauses in it -- as I am sure some of you have observed -- defining foods in terms of adulterated, the seventh clause having to do with defining irradiated foods as adulterated. What I have done in the abstract -- in the body of the testimony -- is to suggest different wording -- somewhat different wording -- than that proposed in the amendment proposed by the two bills under consideration, in order to, if you will, complete that section of the State act where that one clause is missing. There are seven clauses in the Federal act -- the adulteration segment -- and there are six clauses in the State act, the seventh clause having to do with irradiated foods in terms of adulteration being missing, if you will, from that section of the State act.

So, what I am proposing is -- and I have it underlined in the abstract -- is to reconcile, at this level, if not take further -- as an alternative to taking no further action on the bills, to reconcile, at this level, the wording, or phraseology, if you will, of the proposed amendment to maintain that complete consistency and harmony between the Federal and State acts. I go to great lengths-- I will spare you the pain of listening to it. I am not going to read the written testimony, but just refer to parts of it. I go to great lengths to make a case -- not for the first time -- for

maintaining this harmony and consistency, because I say there is absolutely no unequivocal fact-based reason for doing otherwise.

Conversely, there is every good reason -- as a few testifiers have already brought out this morning, and I have done on many occasions in oral and written form in recent months and years-- There is every good reason to maintain this harmony, and no good reason -- no substantiable, unequivocal fact-based reasons -- for doing otherwise.

The other main point I try to bring out in the written testimony is that contrary to what we heard earlier -- and I, for one, have rebutted and refuted each and every allegation, red herring, straw horse, and so forth that has been thrown out this morning, with more to come-- These are all thoroughly rebutted warmed over allegations, innuendos, and so forth, so I am going to leave those alone this time for a change, and just advance the view that to do other than what I have suggested would be to in-advance, or preempt, the right of free choice of the New Jersey consumer.

It has been suggested that a year from now, or two years from when the Food and Drug Administration regulation was published in April, 1986, all forms of labeling, with the possible exception of the international symbol, will be dropped. The food and allied industries, not to mention the radiation industry -- but the food and allied industries made it very well-known to me that regardless of what the Food and Drug Administration does on labeling, they fully intend to maintain factual, informative labeling, not only to the effect that this or that product has been so treated, but the reasons for doing so. When the public gets by all of the inflammatory rhetoric surrounding this issue -- and all of the peripheral issues, and so forth and so on -- I am confident, as others are, that the public will come to appreciate the public health and other benefits of this technology, as applied to foods, and

will gravitate to the irradiated product in a choice over and above the counterpart. For example, when a USDA petition for regulation is completed by the Food and Drug Administration -- it is under active review now -- I can see the day when one or more poultry companies will offer "Salmonella or pathogen-free irradiated poultry."

Then the consumer can cast his vote in the marketplace, with the full knowledge and understanding that the products have been irradiated, and why they have been irradiated. I say that to do otherwise would be in-advance to remove this right of free choice that belongs in the marketplace, in this particular case.

Other public health examples-- I can see the day, not too far off, when pork packers will be packing "trichina or parasite free irradiated pork," with irradiated in the title, along with a symbol. Then the public will have the free choice -- unless bills such as these are passed as they presently read -- to choose certified parasite free pork. This also extends to seafood. I visited with a seafood industry colleague of mine last week at a Coalition for Food Irradiation meeting, and he assured me that the seafood industry has taken a renewed interest in radiation, not simply because of their longstanding interest in spoilage delay and fresh market life extension, but more so now with the proliferation of raw bars and the consumption of raw, uncooked fish and shellfish -- a renewed interest in the context of preventing parasitic food poisoning through these avenues.

So, there is interest out there. There are very important -- as has been mentioned earlier -- and very substantial public health benefits to be gained by this technology which are already being realized in other countries. A few years ago, the Dutch Health Ministry, in response to a public outcry after a very, very serious food poisoning outbreak associated with frozen shrimp coming out of

South Asia -- which made many, many people sick, and killed a number of them -- mandated -- a couple or three years ago -- that these products should be irradiated to rid them -- in the frozen state -- of these pathogens before they could be marketed in Holland. This is just one example. I can see this trend spreading to North America and elsewhere, because it is generally recognized by authorities -- the Food and Drug Administration, the World Health Organization, and so forth -- that the single most serious food-related public health problem in the world is food-borne parasites and microbial pathogens, as one of the doctors mentioned earlier.

Irradiation treatment is a proven tool to reduce Salmonella in poultry, parasites in seafood and pork -- the list goes on and on and on -- and to preclude the right of free choice to opt for these products, if and when they can become available. These bills -- as I pointed out -- are really a preemption of the right of free choice, which should be left in the marketplace, because there is absolutely no fact-based, substantiable evidence that irradiated foods are anything other than safe and wholesome.

I will stop at this point and just, if I may, draw your attention to the list of appendices at the very end of the written testimony. Some of these are in the individual packets. The entire set is in the master packet, if you will, which I have passed on to Mr. Price. This is just a sampling of documentation, documenting just some of the things I have said. I don't have the time to get into a lot of other things that I wish I had. The single largest -- I believe Professor Solberg referred to it in his testimony -- this massive study -- that is number five under Appendix B -- which exhaustively looked for unique radiolytic products over decades-- Actually, this work was started in the 1960s, and was completed in the early 1980s. The overriding conclusion of this work by these scientists is that there are no unique radiolytic products, as Professor Solberg indicated.

The more recent work of the National Bureau of Standards has failed to come up with any unique radiolytic products. They were not searching for them in a public health context, but rather to find a marker that could tell one analytically if a product had been irradiated. They were simply unable to find a bona fide unique radiolytic product that would serve as a marker, or one even that wouldn't serve. That underscores an interesting point, too. With all this talk about these massive changes -- unknown changes -- going on in irradiated food that we hear about from practitioners of alarmist obfuscation, if that be the case, why on earth can't we look, feel, smell, touch foods that have been irradiated and know they have been irradiated? As was pointed out earlier, there is simply relatively so little chemical change going on, that there is no perceivable way of knowing a product has been irradiated. That is the whole reason the Food and Drug Administration opted for labeling in the first place. There is no perceivable way for the consumer to know if a product has been irradiated, unless it is labeled, because the changes are so very few and minor, compared to other processes, where it is readily evident that this, that, or the other thing has been done to them.

So, it is a paradox to claim on the one hand that these massive unknown frightening chemical changes are occurring in foods, and on the other hand to complain that we have to have labeling because there is no other way of knowing if food has been irradiated. Further to that, not only are the changes far fewer in number and kind than those with other energy depositing food processes, but they are infinitely better documented, qualitatively and quantitatively, than for any other food process, the reason being that food irradiation is the only process that was ever classified as a food additive, so exhaustive studies had to be done, in order to establish the toxicological safety of irradiated foods from a chemical standpoint, let alone the biological.

I would just draw your attention, if I may in closing, to a few other things. The research by the Mainland Chinese -- the Peoples' Republic of China -- was dismissed by opponents earlier, yet they embrace a much, much skimpier, shorter term Indian study on polyploidy, that has been thoroughly refuted and debunked, not only by other research centers worldwide, most recently the Chinese studies, but by the Indian government itself. Nobody takes that study seriously any more. It was dismissed -- refuted and dismissed in the mid-1970s, when it was first published. It was resurrected in the early 1980s by those who were reinventing history because they didn't understand what went on before. This study on polyploidy in India is the most refuted and debunked and dismissed study I can possibly think of, but it keeps finding its way into the debate about food irradiation.

The Chinese studies, among other clinical evaluations, looked at polyploidy. These were far more detailed, longer studies, with far more human subjects consuming a variety of irradiated food, including wheat, involved in them. So, to dismiss those as irrelevant, and cling desperately to the polyploidy studies that came out of India in the early '70s, which every responsible scientist and public health official has long ago dismissed, is ludicrous.

The Canadian Parliamentary Report that came out recently-- I would like to touch on that. It has to do with Appendix B-12. This was a report of a very politicized Canadian Parliamentary Committee, the majority of whose witnesses were from organizations such as "Mothers Against Nuked Foods." That was one of them. Mothers Against Nuked Foods was given more weight than the National Consumers Association of Canada, which long ago -- several years ago -- endorsed food irradiation for its public health and other benefits. The National Consumers Association of Canada testimony was given far less weight than Mothers Against Nuked

Foods, a new upstart outfit out in Vancouver, British Columbia. This is the sort of thing that went into that report.

I included in my package a much more detailed, exhaustive, and credible scientific report put out about the same time by the Science Council of Canada. The Science Council of Canada is the Canadian analogue of our National Academy of Sciences, if you will. They examined food irradiation for the better part of two years, where the Parliamentary Committee held about 10 separate hearings over several weeks. The Science Council of Canada reporting to its Minister, like the National Consumers Association of Canada, unhesitatingly endorsed this process for its public health and other benefits, recognizing, through their own exhaustive literature research that there wasn't any substantiable, unequivocal evidence otherwise. I draw your attention to that Canadian report, which has gotten far too little exposure, with all of the talk about the very biased and politicized report of the Parliamentary Committee.

ASSEMBLYMAN COLBURN: What was the name of the Canadian organization? I didn't-- Was it like the National Research Council?

DR. GIDDINGS: Well, it is the Science Council of Canada. It is a scientific advisory body through the Canadian government, which reports through the Minister of Science and Technology of the Parliament, where the other report which is given all the play was done by a Standing Committee on Consumer and Corporate Affairs of the Canadian Parliament. I won't go into the details of how those hearings were conducted, except to say that the majority of witnesses, again, were of the nature of Mothers Against Nuked Foods.

There is a lively debate going on in the Canadian Parliament, simply put, over which report is the more credible one that one should base one's decisions on. It will be a few months yet probably before the results of that are in. We who

are very close to it are confident that the much more credible and competent Science Council of Canada Report will prevail. I might add, a toxicologist-- Interestingly enough, a toxicologist hired for a brief period by the Consumer and Corporate Affairs Committee of the Canadian Parliament, in going over a massive study that has been scrutinized by several groups in detail over the past few years -- they had a few weeks to look at this, but they were handed a dozen other studies selected by the Consumer and Corporate Affairs Committee of the Parliament-- They dismissed half of them. The ones which they dismissed were ones which have already been referred to having to do with kidney lesions, and the polyploidy one itself. The toxicology group which reported to this Committee had the same criticisms -- serious criticisms -- of the so-called reports implicating irradiated wheat with polyploidy that others, including the Food and Drug Administration, had in scrutinizing these reports. In fact, they are in general disagreement on essentially all counts with the Food and Drug Administration and the Canadian Health Protection Branch in Health and Welfare, Canada, yet some gratuitous comments in their Executive Summary were stretched all out of context to provide a pretext for some ridiculous recommendations, including rescinding a longstanding approval of irradiated wheat in Canada, on the basis of this polyploidy nonsense, which nobody takes seriously any more, except people who don't know any better.

I point all of this out because-- I could go on all day -- as you are probably well aware -- and probably well into the night and the next day, refuting -- rebutting and refuting each and every allegation, innuendo, misrepresentation, and so forth that I have heard many, many times in the past. Some of you may be hearing them for the first time today, but, believe me, they are stale and warmed over.

I would just point out a couple of other things. Have studies been done-- Appendix G references a symposium at an annual meeting of the Federation for American Societies of Experimental Biology, an old, august biological sciences confederation. Their fortieth annual meeting in Atlantic City, New Jersey, April, 1956, devoted the entire symposium to work already done, or under way, on nutritional and toxicological studies on irradiated foods. This was in 1956.

Appendix H: In 1966, 10 years later, when the Army Surgeon General declared irradiated foods in sterilizing doses safe and wholesome for human consumption, a group at the University of Massachusetts published an annotated bibliography of just some -- not all by any means -- merely wholesomeness studies, which were done and published in the open literature by 1966. There were over 300 of them. The FDA action in clearing irradiated food applications -- and the number of studies scrutinized and the number of studies used, as has been referred to earlier -- is one of the most utterly misrepresented figments of imagination in this entire debate.

The Food and Drug Administration itself has clarified this, among many other questions, time and time again to anyone who is willing to listen. They are preempted from being at state hearings, but they will be testifying at a congressional hearing that is coming up on Friday on the Hill, which is being held by Congressman Henry Waxman and his Subcommittee on Health and the Environment. The Commissioner of the Food and Drug Administration will be testifying, along with the Director of the Center for Food Safety and Applied Nutrition, to once again clear up these misconceptions and misrepresentations for the record.

The final article I would like to call your attention to on this list is the one by Saundra Aker, Registered Dietitian, Director of Clinical Nutrition at the Fred Hutchinson Cancer Research Center in Seattle. She has attested

publicly on the "MacNeil/Lehrer Newshour" and through the article I have appended to this testimony, as to her excellent results since the early 1970s in feeding immune-suppressed hospital patients, bone marrow transplant patients, and patients under cancer radiotherapy or chemotherapy, with radiation sterilized foods, which she finds superior in eating quality and nutrient retention to the thermally sterilized counterpart.

She has been using these products in her work at that center since 1974 and, as I say, she has attested on numerous occasions to their effectiveness in the fact that they raise the morale of the patients, because the only pleasant thing they have to look forward to each day is mealtime.

I think I will stop there, Mr. Chairman. I could go on and on, naturally, like everybody else in this room, but I think perhaps I have said enough in reference to the written testimony to hopefully draw serious attention to what I propose in the abstract on the front page in dealing with amending Chapter 5-8 of Title 24 if, indeed, it warrants amendment.

Thank you very much.

ASSEMBLYMAN COLBURN: Thank you. How many different foods are being irradiated in New Jersey at the plants?

DR. GIDDINGS: The only food -- in fact, this goes for the entire North American Continent -- related products, other than packaging materials -- a lot of which are being pre-sterilized with irradiation -- are spices and seasonings, as a previous testifier mentioned. Now, this leaves the possible misconception that there is no interest out in the food industry, when this is far from the truth. The fact is, we are in a "Catch-22" situation, Mr. Chairman, right now, where the food industry has a great deal of interest in this process. The Hawaiian papaya industry pushed the U.S. Department of Agriculture to promulgate a regulation clearing papaya irradiation. That is about to be finalized. The

Florida citrus industry has just recently done likewise, and we expect a proposed regulation for the irradiation of Florida citrus for insect control, well within this year.

There is a lot of interest in the food industry. I deal with the food industry every day as a food professional. The interest is not being manifested openly and publicly for a reason too obvious to mention. With this firestone of contrived controversy going on now, the people in the executive suites of these corporations are not prepared to risk their brand names by coming out with their colors flying and attesting to the fact that they are definitely interested in the process. They are doing a lot of quiet testing and evaluation with myself and my company, as well as with others. We know this. We know why they are not coming front and center and testifying, notwithstanding their genuine interest in the process.

But, right now, it is purely spices and seasonings, I guess in part because those are the only immediately acutely needed food irradiation applications.

ASSEMBLYMAN COLBURN: And, on the safety issue-- I notice in the material you gave us there is a diagram that looks to me as if it is addressing the safety issue -- is it, that one diagram?

DR. GIDDINGS: Yes, I included that, although the safety of the facilities and their safety features are not directly relevant to the bills under consideration, as is a lot of the other testimony that has been going on here. I put that in for very genuine reasons. This is an aspect of radiation processing which is on a lot of people's minds, particularly in New Jersey.

ASSEMBLYMAN COLBURN: The amount of material in the plant-- Is that equal to what was released at Chernobyl, or how do we know?

DR. GIDDINGS: I am not sure what was released at Chernobyl, but it is totally irrelevant. The material that was released at Chernobyl was radioactive particulate fallout, which was carried by the winds and deposited in land and water, and found its way into the food supply through these avenues. The safe, encapsulated radioisotope that has been used for years and years in cancer radiotherapy is the same product -- cobalt-60. It is the same product that goes world-wide into cancer radiotherapy units. It is the same product that goes into the processing plants that we and others operate. There is no comparison -- there is no basis for comparison -- between the particulate radioactive fallout that was released by the Chernobyl exposure and what we use in a very safe, isolated fashion in processing in the medical sense in cancer treatment, no more so than comparing the amount of energy one receives with a chest or dental x-ray to what products receive when they are being processed for various reasons, be they food, medical products, or what have you.

ASSEMBLYMAN COLBURN: Okay, thanks a lot.

DR. GIDDINGS: Thank you.

ASSEMBLYMAN COLBURN: May we have Kitty Tucker and Keith Schaeffer come up? They are both from Washington, I think. Good afternoon.

K I T T Y T U C K E R: Good afternoon. My name is Kitty Tucker. I am an attorney. I am the President and Executive Director of the Health & Energy Institute, a public interest research and education organization based in Washington, D.C.

Thank you very much for this opportunity to testify on the subject of food irradiation. I commend the New Jersey Legislature for taking prompt action to protect its citizens from the potential long-term health hazards which might be caused by consuming irradiated foods. I am the co-author of "Food Irradiation: Who Wants It?" to be published in July by Thorsen's Publishing Company. I have testified before the

United States Congress on the subject of food irradiation, and I have submitted extensive objections to the Food and Drug Administration regarding their actions to allow food irradiation in the United States.

We must shoulder our responsibilities to protect our children's health and welfare, not only from immediately discernible dangers, but also from invisible or hidden hazards that can destroy their health, well-being, or ability to bear children when they become adults. We must apply our scientific research skills to assuring that new technologies do not jeopardize long-term health. The Federal government has failed to assume that responsibility in the case of food irradiation. It has chosen to ignore the studies warning of problems and to instead promote a dangerous technology based on "assumptions" of safety. The State of Maine has already adopted a bill similar to the one that you are considering today. I hope that you will provide similar protection for your citizens, and lead the way for other states and eventually for the Federal government.

I am submitting a much longer footnoted document. I will try to summarize and skip over some of the issues already covered by earlier speakers. However, no one has stopped to define what food irradiation is. It is a technology in which food is passed through a beam of ionizing radiation. This ionizing radiation can be created either by a radioactive source, such as cobalt-60 or cesium-137, or by a machine source that generates x-rays or electron beams. The purpose of passing the food through this deadly ionizing radiation is to inhibit sprouting or to sterilize or kill insects and other microorganisms that may be present on the food.

Now, different forms of life have different sensitivities to ionizing radiation. Humans being one of the most complex life forms are extremely sensitive to ionizing radiation. A dose of 600 rads is considered lethal for people

exposed to that dose over their whole body in a short time period. The FDA has approved exposing foods to doses of up to 100,000 rads. Obviously, this means that facilities exposing foods are going to be very hazardous to workers. The sterilizing doses that would kill off all microorganisms on food do have an impact on the foods. An earlier witness stated that we can't tell when foods have been exposed to ionizing radiation. But the early studies in the 1950s showed that when they sterilized foods with very high doses of ionizing radiation, most foods became unpalatable. Recent research has focused on reducing doses to kill off insects or just microorganisms like Salmonella in a frozen state or in a low temperature refrigerated state, where they can reduce the organalectic changes in the food.

The irradiation of chicken or fish to kill off Salmonella has not yet been approved by the Federal government. It is still under consideration by them. The doses that have been approved are doses that will inhibit sprouting, that will kill insects, or that will cause the insects to become sterile within the United States. Although the technology is legal for certain food items in around 30 countries, the process is not yet in widespread use anywhere in the world. The United States will not fall behind the rest of the world if we decide to protect our children from this unproven technology.

Promoters of the process of food irradiation include the International Atomic Energy Agency, current radiation sterilization companies, and various governmental bodies. I understand that the DOE promotion will be addressed by a later witness. The IAEA formed an expert committee which also involved the Food and Agricultural Organization and the World Health Organization, which issued a report approving food irradiation. This has been mentioned earlier. However, I believe this is somewhat akin to the American Tobacco Society

joining with a couple of other organizations in issuing a report claiming that there is no proof that smoking cigarettes is hazardous to your health. People will look at the source of this claim, and then give it the credibility it deserves. The International Atomic Energy Agency is not a public health organization. Its mandate is to promote nuclear technologies.

Opposition to the food irradiation process has been launched by consumer, health, and environmental organizations. Opponents now include local and state bodies in the United States and the European Parliament.

Several of the hazards of exposing foods to ionizing radiation have already been addressed. Malnourished children fed freshly irradiated wheat developed chromosomal abnormalities of the blood. I would like to point out that witnesses have said these studies have been refuted. I think there is a difference between studies which have looked at irradiated wheat, as opposed to those looking at freshly irradiated wheat. The study being cited specifically said the wheat had to be freshly irradiated to produce the unusual blood abnormalities. The recent study being done by the Chinese mentions that they had increased chromosomal abnormalities in the blood of some of the Chinese citizens eating irradiated foods, but they had increases in both the study population and the control group. To me, this is an area of unanswered questions where further research is needed on various animals.

In addition to the studies done by the Indian scientists, studies have been done at the Nuclear Research Center in West Germany, which found no blood abnormalities, and at another center in Great Britain. We are finding studies which disagree in their results, and I think this controversy needs to be resolved before our children become guinea pigs.

Fruit flies fed gamma irradiated chicken had seven times fewer offspring than those fed heat-treated chicken, in a study sponsored by the Federal government and conducted by

Ralston Purina. No one has as yet mentioned the Ralston Purina study, so I would like to suggest a couple of other disturbing findings in that particular series of studies. In one of the studies, they found that more of the male rodents died when they were eating gamma irradiated foods. The researchers suggested they had a number of unusual lesions in this group. Another panel was established to review the slides of these lesions. This panel declared that the lesions were not cancerous and, therefore, there was no problem. Unfortunately, this claim does not answer the question, "Well, why did more animals die when they ate the gamma irradiated chicken?"

Another study that was supposed to look into multi-generational effects was cancelled after only nine months, when it was supposed to run for two years. The researchers claimed, "Well, it is perfectly safe." It seems to me that it is a little illogical to say that you need to look at the multi-generational effects over a two-year period, and then to cancel it after nine months because there were problems with the test animals, both in the study group and the test group.

Chemicals called radiolytic products appear in foods after they have been exposed to ionizing radiation. Some of these chemicals are harmful to human health. Now, we had earlier witnesses state that there are no unique radiolytic products and, therefore, this is a false issue. I am not going to argue with whether or not there are unique radiolytic products, because the scientific literature clearly identifies known dangerous chemicals appearing in food after it has been exposed to ionizing radiation. I am not a chemist, but our chemical advisers tell us they are especially concerned about the alkahydes in substances like benzene and peroxide.

It has already been mentioned that vitamins and minerals are destroyed by food irradiation. Aflatoxins, which are naturally occurring cancer-causing agents, grow more

readily on foods that have been irradiated. I understand a later witness is going to stress this in greater detail, so I will skip over it. Some bacteria are very resistant to radiation and will grow rapidly on irradiated foods, such as the botulism organism. Now, several witnesses have suggested that the problems of Salmonella can easily be solved by exposing all of the Salmonella-bearing products -- meats, poultry, fish, and so forth -- to ionizing radiation. Yet, the recent television documentary highlighting the problems of Salmonella clearly pointed out that the problem has grown because we have introduced mechanical devices to take out the guts from the chicken. They often split open the guts and contaminate the chicken products.

I believe there are safer alternatives that could be established at the large chicken processing plants, such as merely washing all of the chicken at the end of the process line. That could greatly reduce this type of food pathogen problem, without causing new problems.

The environmental hazards of the food irradiation process have not been adequately addressed, and there has been no environmental impact statement. The hazards include: the increased transport of dangerous radioactive materials on the nation's highways; the danger of exposures to workers, which could cause immediate death or could result in later cancers or genetic problems; and the possible contamination of the environment due to continued accidents at irradiation facilities, such as the accidents which have already occurred at plants, several within this State. These concerns all focus on gamma sources -- cobalt-60 or cesium-137. However, even with machine sources, we face the potential creation of dangerous mutant bacteria or viruses. The mutagenic properties of ionizing radiation are not at dispute. The increased generation of radioactive waste has already been adequately addressed by Dr. Johnsrud.

There has been, by earlier witnesses, some discussion of radiation where they have lumped together non-ionizing radiation and ionizing radiation. I think it is very important to understand the difference between these. Ionizing radiation has sufficient energy to change the sub-atomic structure of matter. We are most familiar with the x-ray machine which is present in doctors' offices as a source of ionizing radiation. However, a variety of radioactive isotopes emit ionizing radiation and, as I mentioned, machine sources can also produce ionizing radiation for food irradiation facilities.

When ionizing radiation passes through a living cell, one of three things can happen: It can pass through and cause no harm, or no lasting harm; it can kill the cell; or, it can damage the cell in such a way that the damage is passed on to future cells. Now, it is the cell-killing effect that led to the deaths of the Chernobyl fire fighters. It is the cell-killing effect that is utilized in cancer therapy. The cell-killing effect is also what kills off the insects that are on food and are the targets of food irradiation at the allowable doses right now.

The third effect is what our scientific advisers tell us probably ultimately leads to cancer. The damaged cell that lives on and then, 10, 20, or 30 years later, has grown into a tumor or cancer large enough to be diagnosed. The problem is, unlike when two people get into a fight and one socks the other one in the eye, where the injured party has a black eye and everyone can see the injury, we cannot examine each individual cell of a living body to determine whether or not it has been injured. That is why we are forced to go to animal feeding studies and other mutagenecity tests to look for possible types of damage.

The problems that can be caused by environmental contamination from ionizing radiation are serious and severe. We have been assured by the radiation processors that we should

not worry about that. We have been told that we have a cancer therapy treatment program in this country, and that radiation sterilization facilities are a little different. That is simply not true. According to the Nuclear Regulatory Commission, which licenses these facilities, a typical cancer therapy machine contains 5000 to 12,000 curies of cobalt-60. Yet, the radiation sterilization industry and the proposed food irradiation facilities will use sources ranging from one million to 10 million curies. Because of the lower energy sources of cesium, we are told that they will need about five times as much cesium as they would cobalt-60 to get the same field of energy. These are massive larger quantities of very dangerous deadly radioactive isotopes.

The history of the operation of radiation sterilization facilities in New Jersey -- in Hawaii amply demonstrates that the so-called safe sources that cannot leak cobalt-60 have in the past leaked cobalt-60. These sources are generally stored in big pools similar to swimming pools, and when the sources leak into that water the water becomes contaminated. At International Neutronics, a contaminated pool spilled over, contaminated the plant site, and eventually the contamination spread outside of the building. The company did not report it to the appropriate regulatory agencies, much less the state or local governments. Later, a whistle blower blew the whistle on International Neutronics, and eventually the Federal courts charged company officials for their actions in this cover-up.

Isometics has been cited by the Nuclear Regulatory Commission for similar types of violations. They had a cobalt-60 source that leaked in 1976. It was sealed and stored at the bottom of a pool. Isometics has been cited by the Nuclear Regulatory Commission for: a) over exposing workers to radiation; b) failing to post radiation areas; c) allowing food and cigarettes in the same areas as radioactive materials;

d) operating the facility without authorized personnel physically present; and e) failing to adequately monitor the water disposed into sanitary sewage systems. The last violation was discovered when former workers advised the Nuclear Regulatory Commission that Isometics had conducted unsafe practices, such as disposing of contaminated water from the cobalt-60 pool by dumping it into a toilet connected to the public sewer system. The NRC verified that a pipe leading from a toilet was measurably contaminated in 1979.

It is these types of violations of regulations that lead to the contamination of our environment and that cannot be simply cleaned up. We don't have vacuum cleaners that can selectively gather up radioactive cobalt or radioactive cesium, and clean up the environment for our children and future generations. Cesium-137 is being encapsulated in a water soluble form, and poses even more severe hazards than cobalt-60 in terms of environmental contamination.

The State of Hawaii was left footing the bill for a demonstration food irradiation project in Hawaii that was initially run by the Atomic Energy Commission. They had to spend hundreds of thousands of dollars to clean up the site when the radioactive source leaked into a swimming pool where it was to be stored. They removed it; they took it out through the roof and contaminated the roof of the building and the surrounding land area, and only discovered that the contamination had not been properly cleaned up in 1980. That means that for many years citizens walked by that building and were unknowingly exposed to ionizing radiation.

It is very, very difficult to regulate and protect citizens from these types of processes, and because we have ultimate processes for assuring an adequate food supply, I do not think we need to go into ultra-hazardous food irradiation technologies.

There are no tests available yet which will identify if foods have been exposed to ionizing radiation. Thus, port authorities or other governmental regulators lack the necessary tools to monitor whether food has been irradiated and properly labeled. Foods could be irradiated and sold without the required logo, or they could be labeled irradiated when the process had not even been used. Obviously, it is very easy to engage in fraud and not get caught here.

Food items, such as shrimp, highly contaminated with bacteria and turned away from a British port, have been irradiated to lower the bug count, and then illegally reexported to Britain. Proper regulation of this dangerous process cannot be assured without the ability to test foods for exposure to the process. We believe that for this reason alone it would be prudent to ban irradiation until we can determine whether or not the process has been used.

Environmental hazards from irradiation facilities similar or identical to those which might be used for food irradiation have been demonstrated in the State of New Jersey, and I have just cited some of the examples. But, the environmental contamination lasts not merely for the half life of the radioactive isotope, but for 10 to 20 half lives, according to our scientific advisers. With half lives of five years or 30 years, that means we ought to be concerned for some 50 to 100 years in the case of cobalt-60, or for the 30-year half life of cesium-137, 300 to 600 years.

Food irradiation is an expensive and unnecessary process which is being forced upon a reluctant food industry by governmental pressures and the lobbying of a small industry which currently uses radiation to sterilize medical equipment. We, and other organizations, have been polling the food industry about their position on food irradiation. Most companies have responded that they are not now using the process, and do not have any immediate intention of using the

process. We have also learned that a number of companies that initially joined the Coalition for Food Irradiation have recently withdrawn.

While a number of organizations both nationally and internationally have declared the process safe, the scientific data and research on the process does not support such claims. We believe a number of groups approved the process without all of the relevant information. We believe that groups like the American Medical Association were presented with the studies that suggested the safety of the process, and have not had an opportunity to review some of the studies raised by scientists today.

We urge the State of New Jersey to protect its citizens by banning the sale of irradiated foods, because the problems that can occur will not be immediately apparent. The long-term health consequences will be very expensive for the State of New Jersey, because diseases like cancer are very expensive diseases, and the State often ends up picking up the bills for poor people who contract such diseases. We believe it is also prudent to protect the citizens of the State of New Jersey from further environmental contamination by discouraging the introduction of the technology that uses dangerous radioactive isotopes.

A number of the other issues we address in our longer testimony have either already been addressed, or are being addressed in greater detail by subsequent witnesses.

I would now like to introduce my associate, Keith Schaeffer.

K E I T H S C H A E F F E R: Good afternoon.

ASSEMBLYMAN COLBURN: Good afternoon.

MR. SCHAEFFER: I appreciate this opportunity to testify before you today in favor of a ban on the sale of irradiated food in the State of New Jersey. This gets me out of the office for a day, too, and I appreciate that.

Some of the things I am going to touch on today have already been talked about, but I intend to go into a little more detail.

ASSEMBLYMAN COLBURN: Do your best to either just mention the things that have been discussed adequately, or avoid them completely, and concentrate on the things -- if you can -- that we haven't heard. I know it is hard to interrupt a prepared presentation to do that.

MR. SCHAEFFER: Okay. Well, two of the claims we have heard touched on today that are often advanced in favor of developing food irradiation technologies in the United States are that: 1) Irradiation is used and is widely accepted in other countries, and that irradiation will open up new foreign markets for our surplus goods. It seems to me that the evidence has been mounting during the last few months to dispute these claims. We have already heard about the Canadian studies and the European community. It is obvious that the major technologically advanced nations in the world are not about to use radiation to any great extent at any time in the near future, and that there are serious doubts among the general public, the governments, and the scientific communities of these nations about the safety of eating irradiated food, and that there are no receptive overseas markets for our irradiated food.

The European Parliament, as mentioned earlier, is made up of 12 member countries of the European Economic Community. They passed a resolution on March 10, 1987 rejecting the general authorization of food irradiation in the European community. The Parliament considers the safety of eating irradiated foods to be unproven, and recommends that before irradiated foods are freely traded among member states, that it must be possible to scientifically determine whether a food has been irradiated or not. Ms. Tucker has already told you what the implications of that are.

The resolution called for a ban on imports of irradiated food and animal feed from nonmember states. The Parliament believes that the shortcomings in current methods of food preservation could be more satisfactorily met by preventative hygiene than by irradiation.

In the United Kingdom, the British Medical Association, also in March, 1987, released a report following their review of a 1986 study by the Government Advisory Committee on Irradiated and Novel Foods. The British Medical Association concluded that more scientific data is required before food irradiation can confidently be accepted in the United Kingdom. The BMA warns that the government report, which was favorable to irradiation, may not sufficiently take into account possible long-term medical effects of eating irradiated food.

Food irradiation is currently illegal in Great Britain and, according to a Marplan Opinion Poll conducted there in January, 1987, an overwhelming majority of the people there prefer that it remain illegal. Eighty-four percent of those polled said that the current ban should remain, and if the ban were removed, only 13% said they would buy irradiated food. It doesn't look like there is any great opportunity for exports to England.

Regarding Canada, several people have already mentioned the Standing Committee on Consumer and Corporate Affairs' report to the House of Commons there. Dr. Giddings was annoyed that-- He said that the overwhelming majority of the people testifying there were opponents of food irradiation, people like Mothers Against Nuked Foods. Well, I have the report here, with the list of witnesses and submissions, and I see a great variety of people testified from the Department of Health and Welfare and the Department of Consumer and Corporate Affairs, and the Atomic Energy of Canada -- which is very pro-nuke and provides most of the cobalt-60 in the world -- had

at least four people testifying. The Canadian Advisory Committee on Food Irradiation had another four or five people testifying. All in all, the testimony took place during 10 public meetings, where they heard testimony from 40 individuals representing the federal government and university and consumer and voluntary organizations. Apparently those in favor of irradiation were not able to convince the members of the committee that food irradiation is safe.

Following the hearings, three out of four members of the committee who appeared at a press conference said that they would prefer not to eat irradiated foods. There is currently no commercial food irradiation facilities in Canada. Many safety concerns were raised by the committee, who concluded that expanded approvals for food irradiation should not be given in Canada right now, and that they wished to rescind the allowances given for irradiating wheat. The major safety concerns raised were: the possibility of chromosome abnormalities caused by irradiated wheat -- and possibly other grains; the possible adverse effects from free radicals and radiolytic products of irradiation; the potentially harmful products produced by irradiating pesticide residues on food; the production of cancer-causing aflatoxins; the possible creation of mutant strains of the mold by irradiation; and the degradation of nutritional quality of irradiated foods.

We have heard here today about the possibility of reducing Salmonella contamination by the use of irradiation. The Standing Committee there points out that irradiation will not get at the root cause of Salmonella, and they recommend that methods more cost-effective than irradiation be pursued to control the problem in Canada.

In Australia, Dr. Neal Blewett, who is the Federal Minister for Health in Australia, says that food irradiation will not be developed as an industry in Australia "in the near future," and adds, "We may never have food irradiation."

There was recently a report sponsored by the Australian government, and done by the Australian Consumers Association, which pointed out that as the debate on safety issues continues, there are serious questions as to the number of countries which will allow the importation of food which has been irradiated in other countries. Once again, not much chance of exporting our surplus food that has been irradiated.

Japan was one of the first countries to market irradiated foods. They allowed irradiation of potatoes back in 1972. A report for the Hawaiian Legislature by the engineering and radiation consulting firm CH2M Hill concludes that Japan is not a receptive market for irradiation products. In fact, I believe it is illegal to import irradiated foods there.

MS. TUCKER: Except for potatoes.

MR. SCHAEFFER: Except for potatoes, and I understand that those are not labeled. The report from the pro-irradiation firm CH2M Hill states: "The two groups that could receive the greatest benefit from broadened applications of irradiation do not want to jeopardize the base of customers or constituents by publicly supporting the process." Also, as far as the export market, it is reported in "Food Chemical News," June, 1987-- Our own Department of Agriculture says that the current potential for international trade in irradiated food is very limited at best and is, for the most part, nonexistent.

ASSEMBLYMAN COLBURN: One of the things that strikes me is, I am not sure that our Committee is going to worry a lot about whether something could be sold that is produced. We are concerned about what it does here; you know, what it does to our own population in the United States, not whether there is a market here, there, or anywhere else. The point has been made that maybe there isn't a market. We've heard that.

MR. SCHAEFFER: Right, okay.

ASSEMBLYMAN COLBURN: Do you have any additional things that no one else has said?

MR. SCHAEFFER: Well, I would like to comment on a remark made by Dr. Fey a little while ago. He indicated that Germany is now using food irradiation in place--

ASSEMBLYMAN COLBURN: Instead of ethylene oxide.

MR. SCHAEFFER: I have here a list of countries that are irradiating food now supplied by the International Atomic Energy Agency Newsletter on Food Irradiation. They mention some 32 countries where certain regulations have been passed allowing food irradiation. We contacted many or of the embassies in Washington, D.C. last fall, and they--

ASSEMBLYMAN COLBURN: And they don't list Germany?

MR. SCHAEFFER: Well, they list the Federal Republic of Germany, but didn't indicate whether it was West Germany or East Germany. The Federal Republic of Germany, according to this-- There is no date of approval. It looks like they allow sterilization for hospital patients of deep-frozen foods, and they do allow some test marketing of potatoes.

ASSEMBLYMAN COLBURN: Okay.

MR. SCHAEFFER: The German Democratic Republic allows the irradiation of onions, enzyme solutions, and some provisional irradiation of spices, but that is all they allow, so it doesn't look like--

ASSEMBLYMAN COLBURN: What is the date of that?

MR. SCHAEFFER: That was in April, 1987.

ASSEMBLYMAN COLBURN: Okay.

MR. SCHAEFFER: Besides pointing out, though, that there is no export market for food irradiation, I believe that the scientific and government bodies went over this issue many times, and they have very serious concerns about the health and safety aspects of food irradiation. We feel that the United States has the same concerns, and we think that is a very good reason for supporting this bill before you today to ban the sale of irradiated foods.

ASSEMBLYMAN COLBURN: Thank you. Edward Remmers?

D R. E D W A R D G. R E M M E R S: I am pleased to very strongly support food irradiation in the United States. First of all, I represent the American Council on Science and Health, but I also represent about 9000 Americans who die every year from food poisoning, two million to four million Americans who get a very severe case of food-borne illness every year, and I represent a part of our 240 million people in the United States who wish their legal right to free access to irradiated food and to capture a portion of the $2 billion to $4 billion in economic benefits that will result from food irradiation.

The American Council on Science and Health is a nonprofit, independent consumer education association that was founded 10 years ago by a retired Harvard professor and one of his students. We were founded to go after the misuse and abuse of science when it is applied to public health issues, particularly in the area of health fraud and nutrition quackery. We are very well known for our anti-tobacco efforts, our anti-AIDS programs, and our emphasis on the 10 leading causes of preventable death in the United States.

Our major effort is to keep the focus on major significant causes of death and health risks in the United States, and get the focus off of insignificant or hypothetical causes of health risk in the United States. When we look at food irradiation, we are very much dealing with hypothetical insignificant health risks. Instead, it is my very respectful opinion that the New Jersey Legislature could do much more to protect the health of New Jerseyans by emphasizing the leading causes of preventable death in the United States, and not take any action in the area of food irradiation.

In 1982, our Consumer Education Association, which is directed by 200 distinguished scientists and physicians in the United States, reviewed all of the literature on food irradiaiton, and published our booklet endorsing the use of food irradiation. Again, in 1985, we re-reviewed all of the

literature and came to the same conclusion, that the vast and overwhelming majority of information on food irradiation supports its adoption.

One of the things we do at the American Council on Science and Health, unlike almost every other group that is represented here today, and unlike many scientific bodies, is, we extensively peer review all of our literature to make sure that we represent the mainstream scientific viewpoint. If you take a look in out irradiated food booklet-- Our booklet was peer reviewed by about 48 or 50 distinguished food scientists, toxicologists, physicians, epidemiologists, etc., before they reached their opinion that the overwhelming, vast majority of data strongly support the use of food irradiation.

I should mention that the American Council on Science and Health does not receive one penny from the gamma radiation processing industry. Also, we have lost nearly all of our funds from the food industry because of our very strong position against tobacco. When Philip Morris and R. J. Reynolds bought out General Foods and Nabisco about 18 months ago, we lost our financial support within a day or two after those financial takeovers. So we know we are getting our message across, and that the tobacco companies are very much aware of our efforts to oppose them every inch of the way.

We strongly oppose the tobacco industry and we strongly oppose the natural organic health food industry, where they are making drug claims for food supplements. They are trying to get the American consumer to buy so-called pesticide-free food, when if you do chemical assays on their food, you will find that they contain actually the same amount of pesticides, or more pesticides. We are also concerned about health food stores dispensing inaccurate nutritional information.

In terms of food irradiation, I mentioned that we have endorsed it as far back as early in 1982. When I was a

graduate student 35 years ago, I started eating irradiated food, when irradiated food began on a very serious basis in 1943. Since 35 years ago, I have been eating irradiated food when I have had access to it.

Now that the Food and Drug Administration has ruled on safety and efficacy, the only two criteria that are permissible under law before approving a drug or a new food process or a new food ingredient, there are no other considerations that may be brought to bear in terms of access to people. If they want to eat irradiated food, they should be permitted that right of free access.

I mentioned that 35 years ago I began eating irradiated food, and have been eating it subsequently. About 23 years ago, I was in the pharmaceutical industry, where many of our sterile injectable pharmaceutical products were sterilized by radiation at doses in the neighborhood of 20 to 30 times the level that has been approved for low-level food irradiation. Surgical sutures have been sterilized by irradiation for many, many years, and yet there has been no evidence of the radiation causing any harm to these human beings.

Unfortunately, from the standpoint of the opponents, when I began eating irradiated food 35 years ago, there were no opponents around. When I began irradiating sterile pharmaceuticals about 25 years ago, there were no opponents around. This raises a very strange question: Why has the opposition to food irradiation only started in the last 18 months or so? I have never been able to get a satisfactory answer to that particular question, among a whole lot of other questions, which I will get into in a few minutes.

As I mentioned, the vast, overwhelming body of peer-reviewed scientific and medical literature strongly supports the adoption of food irradiation. It has been endorsed by a whole lot of organizations, probably 50 or so

scientific, as well as medical organizations. It has not been opposed by any scientific or medical groups. It is certainly supported by the vast majority of knowledgeable mainstream scientists and physicians. It has been used in about 35 countries since 1958. About 1.5 billion pounds of irradiated food is being produced every year, and there has not been one reported case of death or one reported case of illness, headache, fallen arches, or ingrown toenails from eating irradiated food. This is since 1958. It is increasing at the rate of about four to five countries a year. It has been more studied than any other food process or any other food additive that has come down the turnpike at us.

The chemical changes in irradiated food are far less than the chemical changes that occur in other food preservation processes. One of the things you will find about opponents of irradiated food is that they never like to compare it with other methods of food preservation. There have been numerous animal and human feeding trials on human volunteers and military personnel. They talked about the Chinese medical students, the conscientious objectors, the cancer patients in Washington, the Russian and U.S. astronauts, and about 1.5 billion people around the world who are presently consuming irradiated food, and there has not been one case of illness that I have come across that would cause any questions about irradiated food.

In my opinion, irradiated food offers very important economic and public health benefits. It is one more tool in the arsenal against -- to improve America's already high-quality food supply, which is already the best food supply in the world.

To qualify as a bona fide critic of food irradiation, I would like to ask critics about 10 questions. I expect that before a critic can really earn his spurs and his stripes as a bona fide critic of food irradiation, to at least pass this little quiz with a score of 75%.

ASSEMBLYMAN COLBURN: Before I allow you to go on with that-- You give us the questions, and we will consider whether to ask them. But, let's not have them responding to you right now.

DR. REMMERS: I am not asking them to respond.

ASSEMBLYMAN COLBURN: Well, it sounded like you might.

DR. REMMERS: No.

ASSEMBLYMAN COLBURN: Are those questions in your written statement? Yes, I see them right here.

DR. REMMERS: The first one is, have you ever eaten irradiated food?

ASSEMBLYMAN COLBURN: Okay.

DR. REMMERS: Most of them haven't. Have you ever visited an irradiation facility--

ASSEMBLYMAN COLBURN: Don't answer these questions.

DR. REMMERS: --even though the irradiation facilities offer tours through their facilities to the people who are not familiar with these kinds of facilities.

Have they ever talked to the personnel working in these facilities, to see their lack of concern about safety? Have they talked to the neighbors-- (response from audience)

ASSEMBLYMAN COLBURN: I knew you would answer these questions, one way or another.

DR. REMMERS: --across the street?

ASSEMBLYMAN COLBURN: Please, let us do the-- We'll worry about getting the answers to these questions, or you can send them in, because we will hold the record open so we can receive additional information for, oh gosh, about four weeks, we'll say. So, please do not answer any questions. Thanks.

DR. REMMERS: Have they talked to the neighbors surrounding these plants to see what their concerns -- actually their lack of concerns are?

Have they ever been associated with any academic or research institution doing any work on food irradiation?

Before I debate any opponent of food irradiation, I want to check out what he has done. I have yet to find any opponent of food irradiation who has been affiliated with any academic or research institution in the United States that has done any work on food irradiation.

UNIDENTIFIED SPEAKER FROM AUDIENCE: I have one right here for you, Mr. Chairman.

ASSEMBLYMAN COLBURN: I asked you, please-- Now, I'm serious. Please do not answer the questions.

DR. REMMERS: Have any opponents of food irradiation published any original research on food irradiation in a peer-reviewed scientific journal?

Have they submitted any comments to the FDA Commissioner? Before the FDA Commissioner approved food irradiation in April, 1986, he had a comment period where anyone could write in any questions, any concerns to him. Before he approved food irradiation, he wrote a preamble, in which he addressed 75 scientific concerns that people had written him about. Almost all of the issues that have been raised here today were answered in that list of 75 comments in the preamble by the Food and Drug Administration.

It would seem to me that a bona fide critic of food irradiation should have submitted his comments to the Food and Drug Administration, and had his comments addressed there. But, instead, the critics of food irradiation like to dredge up some experiments which have usually been rejected for very good reasons. They try to build a whole case -- a house built on sand. Really, if you study it very carefully, you will find that the FDA Commissioner has addressed, very nicely, almost every one of the issues that have been brought up here today.

Most of the critics of food irradiation have not read the preamble to the FDA Commissioner's approvel. If they had read the preamble, I don't think they would be raising a lot of these issues, as they are.

Why did they start opposing food irradiation only in the last 18 to 24 months, when the technology has been around for many, many years? As I said, when I was eating irradiated food 35 years ago, there were no opponents around.

As I sat through the hearing today listening to the opponents, I kept running into the same observations. They never like to talk about the chemicals in irradiated food that seem to be of concern to them. My concern is, I don't think they know how to pronounce those chemical names, and I don't think there are any names--

ASSEMBLYMAN COLBURN: That was an unnecessary comment, too, I think.

DR. REMMERS: Well, it is an observation that they never talk about this. I would like to check out these chemicals.

ASSEMBLYMAN COLBURN: I am attempting to run this thing in an objective manner. I think references which would tend to demean someone else are unacceptable. I realize you are not the first one to raise any, but, you know, really and truly, I am sitting here very patiently, trying to figure out as much as I can. I would appreciate it if we all treated each other with more courtesy.

DR. REMMERS: I would like to get a list of the names of those chemical compounds that opponents of food irradiation are concerned about. I feel they are evading the issues by failing to mention the chemical names, so that a group of toxicologists, research physicians, and others could take a look at that list of chemical names and check out the toxicology of those particular compounds.

I have offered this challenge to opponents of food irradiation previously, and the vast majority of them have not accepted this challenge.

Another key question to establish one's self as a legitimate critic of food irradiation is, they must describe

the scientific mechanism by which they believe harm will be caused by the consumption of irradiated food. They like to side-step this issue, very, very much so.

The last question I ask is, can you list future experiments you would like to see done that would fill in these so-called gaps in knowledge, so that you would become very enthusiastic supporters of food irradiation? Here again, you do not get a straightforward answer.

Specifically, what I would like to see is the kind of experiments they would propose, what kind of irradiated food would be served, what animal species, how many repeat groups, how many different parts of the world would this experiment be done in, who would be monitoring these experiments to build validity into the experimental results, and, lastly, who is going to pay for these very, very expensive experiments? When you ask these hard questions, you keep getting zero in terms of answers to just about every one of them. I have yet to come across an opponent of food irradiation who scores very high on this particular exam to qualify as an opponent.

For the past 18 months or so, I have been closely monitoring the various publications opposing food irradiation, the various public statements on radio, TV, and elsewhere, and newspaper articles. So far, I have debated 12 of the East Coast critics of food irradiation. I would like to share a few of my observations with you. They focus on the insignificant hypothetical risks, and ignore the major real health risks that are facing Americans, as well as New Jerseyans.

Certainly, cigarettes, AIDS, excess alcohol, seat belts, and smoke detectors are the areas where the New Jersey Legislature could really do a service for people by protecting the lives of New Jerseyans.

The opposition to food irradiation is based on fear and emotion. If you take a look at the publications coming out of these groups, you will find that they are trying to link,

incorrectly, food irradiation with Chernobyl, Three Mile Island, South Africa, Bhopal, Thalidomide, Diethylstilbestrol, and a whole host of other totally irrelevant issues.

I mentioned that critics of food irradiation evade discussion of the real issues. I still want to get a list of chemical names of the chemicals in irradiated food that they are concerned about. You will never get such a list. I think, to move this discussion along, it would be nice if your Committee here would ask for such a list of chemicals they are concerned about in irradiated foods; also, the scientific mechanism, as well as the future experiments they would like to see.

Calls for future testing, and we need more testing, are really nothing more than a thinly disguised effort to try to delay this important key technology. Opponents of food irradiation use food irradiation as a front for their not-so-hidden agenda to advance their political, philosophical, and personal views. We certainly have the anti-nuclear groups trying to block any further application of nuclear energy, regardless of the benefits. They are bluntly unable to take an objective view of any new application of radiation. Their minds are made up in advance. Even though they may have, on paper at least, fairly respectable academic credentials and positions, nonetheless their anti-nuclear views just overwhelm them, and they are unable to look objectively at a very beneficial application of nuclear energy.

They speak far more eloquently on Department of Energy and Nuclear Regulatory Commission regulations than they do on the science and technology of food irradiation. You run into environmentalists who are concerned about the outdoor environment, but they will never once talk about the indoor environment, where New Jersey's pollution problem really is, with radon and cigarette smoke. They like to focus on the outdoor environment, where the problem isn't, to keep the heat off the indoor problems.

Then you have the natural organic health food stores, which are largely financing the opposition to food irradiation. These are the people who would like us to pay 50% to 100% more for our food in a natural organic health food store, when really that is not necessary. They are going on the assumption that the American people feel that the American food supply is grossly contaminated, when it isn't. They try to offer their food supply as being pesticide free. When you do a chemical analysis on their food and compare the analysis with food coming from a traditional food store, you will find that the natural organic health food store's food actually has more, or the same amount of pesticide residues.

Certainly, you have the alternative health care holistic medicine lobby in conflict with the FDA over a lot of issues. You will find that food irradiation is just one more issue on which this alternative health care holistic medicine lobby can try to browbeat the FDA.

Then, lastly, some opponents of food irradiation are using their personal publicity to further personal financial objectives by promoting their services and product lines. (much reaction from audience)

ASSEMBLYMAN COLBURN: Kindly just-- You know, we can separate all of these things. Please don't help us too much.

DR. REMMERS: Opponents of food irradiation want to deny New Jersey consumers free choice, now that irradiated food has been approved for safety and efficacy. In my opinion, irradiated food should be made available. This ill-conceived legislation is only designed to placate the activists and, really, it ends up depriving New Jersey citizens, in advance, of the public health and economic benefits of this important new technology.

Thank you.

ASSEMBLYMAN COLBURN: Thank you. I am just counting how many people haven't gotten a chance to speak -- one, two,

three, four, five, six, seven, eight, nine, ten, eleven. Dr. Piccioni, do you have anything? Can you tell us anything we haven't heard yet? (indiscernible response from Dr. Piccioni from audience) Well, would your testimony add things we haven't heard? (affirmative response) Okay, well, come up here and summarize it, will you? We have had some pretty long reports. (applause) It sounds like you have brought some fans.

DR. PICCIONI: No, I didn't bring anybody. I brought one co-worker.

ASSEMBLYMAN COLBURN: I know.

DR. PICCIONI: Could you do me a big favor?

ASSEMBLYMAN COLBURN: Sure, I'll try.

DR. PICCIONI: I don't like to testify with a video camera--

ASSEMBLYMAN COLBURN: Oh, is there a video camera?

DR. PICCIONI: Yes. Can you--

ASSEMBLYMAN COLBURN: Oh, where is it? Well, I'll tell you, I think if a witness doesn't want it on, we ask that it be turned off. I didn't even know it was there.

DR. PICCIONI: Fine. My name is Dr. Richard Piccioni. I have a Ph.D. from the Rockefeller University. I got it in 1977, and then worked three years as a post-doctoral researcher there. I was with the City University of New York as an Assistant Professor of Biology for an additional five years. I am Senior Staff Scientist -- that is a voluntary position, a nonpaying position -- with Accord Research and Educational Associates. That is a not-for-profit environmental research group, that is composed of a number of professional volunteers, physicians, statisticians, and several systems analysts -- you know, programmer types. We have been, over the past several months, carrying out a study -- our own research study -- of literature -- scientific literature -- on food irradiation, we well as the legal procedures that accompanied its approval by the FDA.

So, what I have given you -- just to go through it very quickly -- is, first of all, a listing of three sets of published scientific reports, and then a summary -- a little bit of history of the FDA. That is basically what I would like to present to you, in as a succinct a manner as possible. I must commend you on your heroism and stamina for putting up with--

ASSEMBLYMAN COLBURN: Well, I had begun to think my brain had been washed, but I can see that this is pretty good stuff here. (referring to materials submitted to the Committee by Dr. Piccioni)

DR. PICCIONI: Let me try a different tone, anyway. Okay. First of all, the FDA has said that food irradiation is safe and should go ahead. That is sort of a long story cut short. Clearly, what we are considering here is a State law which would, very directly, question that decision. Now, first of all, if there is any concern about this, I don't know. There is plenty of precedent for the FDA having made mistakes. That is the subject of the last seven pages of my handout. It is kind of a review of the history of mistakes the FDA has made; substances that they allowed on the market longer than they really should have; substances that are still on the market when there is quite a bit of evidence that they are doing people harm. So, I think there is every bit of legitimacy to the idea that a state government that represents a large number of people can consider legislation that questions the FDA's decision.

Now, the other point I want to make about the FDA's decision is, the situation with food irradiation is very, very different from really any other approval that I know of that the FDA has considered. It is because of some very basic physical aspects of food irradiation as a process. It is a very interesting kind of a situation. See, years ago they said, "Food irradiation should be treated as an additive." I

don't know if it was foresight or just wisdom, or whatever, but they are right. It is a very accurate assessment. Why? Because it is universally accepted that when you dose organic materials, like food, with high doses of radiation, you produce significant quantities of chemicals -- of substances -- that weren't there before you irradiated them. So, in effect, you add these substances to the food. It is effectively that way an additive.

Now, the problem, you see, with food irradiation -- the regulatory problem with food irradiation -- is simply this: You cannot take a bottle that comes off the shelf of a chemist, which is the additive, and test that additive on experimental animals in concentrated doses. That procedure is the basis by which the FDA approves pesticides, food additives of various kinds, residues, and so on. You see, that experiment is essential in determining toxicological safety, when you are talking about things like cancer, or mutation, where what you are worried about is not that, you know, every person who eats, or is exposed to, this substance is going to keel over dead. But, rather, that you are going to be introducing into the food supply a small, but definitely real, carcinogenic agent which, distributed over millions of people consuming food for their whole lives, will cause real deaths. The only way to determine whether that is going to happen or not is to somehow obtain, in concentrated form, the material you are putting into the food.

If you can't do a test like that, where you have the material in concentrated form to test, you really cannot point to any feeding study as being evidence of safety. The FDA agrees with this. They have made this very clear from the beginning, that they don't believe that traditional toxicological feeding studies will really solve the problem. You can look, for example, at the April 18, 1986 "Federal Register" announcement. It presents what has been said many

times by them before, which is that the problem is that you can't concentrate the substances you are concerned about, and test them at high dose. Therefore, any feeding study is going to be very deeply and very seriously flawed. That is the problem, you see.

What they have had to do is come up with another way around this issue because, on the basis of direct feeding studies, they could never show that irradiated food was safe. If you take irradiated food and you chop it up into little pieces and feed it to mice, that is testing the concentration times one. And typically when they test additives, they test the concentration times hundreds of thousands fold. Talk to any toxicologist, and he or she will explain this in this way.

Now, how did they get around that problem? The way they got around the problem primarily was to develop an argument based on theoretical calculations of what could be the maximum amount of what they call unique radiolytic products present in the food after irradiation. They came up with a number which for 100 kilorads is three parts per million. Now, one could go into a long discussion about three parts per million being actually rather high, when you don't know what it is that you are talking about. You don't know what it is three parts per million of. You see, no one has come up with, and no one is going to be able to come up with a complete list of the substances that are produced when you irradiate food. The process is much too complex. You are introducing this very concentrated form of ionizing energy in a very complicated molecular environment, and the changes are myriad. Substances will be produced in the part per million range; in the part per billion range. When you don't know what it is that is being produced, how can you say that the quantity that is there is safe?

This, I believe, is a very crucial problem with the approvals the FDA has passed. I think -- and the legal people

in our group agree with me, or actually they convinced me -- that this is in violation, essentially, of the Delaney Amendment; that you cannot approve the presence of substances whose toxicity cannot be tested; indeed, whose identity is not known. So, that is a very crucial point.

Now, an enormous amount of work has been done in studying substances which are produced by radiation treatment of foods, but it is a drop in the bucket. What they have found is a drop in the bucket compared to the amount -- potential quantity and variety of substances which need to be tested. It is like looking for a needle in a haystack, or actually worse. It is like looking for a piece of hay in a haystack. It is very difficult.

Now, the FDA reviewed -- in spite of the fact that they themselves said that toxicological studies themselves will not prove safety -- a large number of them. They went through this winnowing procedure, which is reasonable, and they came up with studies that they thought were valid. It is rather extraordinary that they came up with only five. Now, we, as a group of scientists, questioned this. We went back, and we looked at the original scientific literature ourselves. What you have on the first and second pages -- sorry, second and third pages of this handout -- is a list of published articles which show positive mutagenicity or cytotoxicity in food, or organic materials, which have been irradiated. So, in fact, in the scientific literature -- and I don't pretend that this is all of it either; these are what we found so far-- In the scientific literature, there are lots of reports of biological effects in irradiated organic media. I don't understand why the FDA chose to ignore these. We have a list, actually a bibliography, we got indirectly from the FDA, which lists those reports they looked at. About half of these are on there; about half of them are not.

Now, mention was made a little while ago of specific substances. Now, again, I must stress that this list is by no means complete. It is only the tip of the iceberg. But, on the following page, you have a list of specific known mutagens and carcinogens that have been found in irradiated foods or food components. These have been found. We know that this must be a list that is only partial. So, here you have the agency approving, on the basis, I think, of a very dubious argument, that they don't have to test further, while there is, in fact, evidence available in the literature that there are biological effects of irradiated organic material, and there are identifiable compounds that are known to be mutagens and carcinogens, which perhaps explain those effects that have been observed.

There are a number of different aspects to this problem, which by now you must be aware. There is another one I just want to touch on, because it points out the fallibility of the FDA's procedures. They mentioned, in their April 18 "Federal Register" announcement a single study that shows that if you irradiate grains, the production of aflatoxin by the Aspergillis flavus fungus that can grow in there is enhanced -- is increased. They mentioned one study. We found five. I don't know what to say more than that, except that these are very interesting studies. They show both effects due to mutation of the organism itself, and modification of the structure of the grain that is being irradiated. In some cases, there are extremely large increases in the aflatoxin, right at the radiation dose that they intend to use on grain. The FDA does not acknowledge the existence, much less the validity of these experiments.

Now, this whole history, then, that has been going on of the FDA approvals, is very odd from a scientific point of view. They have taken a very-- It is understandable that they had to do something, because, like I said, again, just the

straight testing of the toxicity or the carcinogenicity of irradiated foods, using the foods themselves-- Any scientist will tell you, "Well, that is not going to be sensitive enough. You need the thousandfold or the hundredfold increase in sensitivity you get when you can concentrate. They have taken this kind of an end run around that issue but, in doing so -- even in doing that, they have ignored existing studies. So, I think this is a very serious problem.

You have probably heard enough about the Canadians. I just want to make sure that this isn't general, along the lines that you are not alone, or you would not be alone, in being concerned about this scientific, technical basis of the approval. There are many, many scientists and public health officials around the world who are concerned in this way. A lot of their concerns were expressed in letters which have been written and published in editorials, and we can provide you with any number of these that you want. We can provide you with all of them.

The study that was conducted by the Canadians-- They hired a professional toxicology firm to evaluate the studies that the government had said proved the safety of irradiated food, and they disagreed. They simply disagreed. They said, "These studies do not prove that."

So, you know, that is basically-- I don't want to take up any more of your time. Please appreciate the difference between proving that something is safe, and simply saying, "We have followed the procedures which have been outlined by the FDA, and we see nothing." You see, it is easy to see nothing, but the problem is, is there something really there? Our results show you that there are things there; that there is evidence in the literature that there are substances which have already been shown to be there. So, it isn't even like there is a question.

ASSEMBLYMAN COLBURN: Do you think that you or someone else would be capable of constructing a study which would lead to a conclusion that would be less assailable than you would feel these are?

DR. PICCIONI: There is one possible approach to this, which has been brought up by a number of people, which is to take large quantities of irradiated food and subject them to chemical extraction procedures using, let's say -- you would have to use a variety of solvents -- and try to remove from the food classes, all compounds that you suspect will hopefully, all together, include anything you might be worried about. Concentrate those down and test those in an experimental system, where you have now that magnification factor you need.

Now, there are a lot of problems with that procedure. How do you know you are getting everything? How do you know it isn't deteriorating? How do you know that it isn't getting more mutagenic, or less mutagenic? But, other than that, I don't see how you can solve the problem, because with Red Dye #2, or Blue Dye #6, you can get a chemist to give you a bottle of it so that you can test it in mice at high levels. But, you can't get anyone to give you radiolytic products, much less one at a time, much less for all the variety of foods we are going to be irradiating, and have them tested at high concentration. Without that, you are taking away the most basic tool of the cancer toxicologist.

ASSEMBLYMAN COLBURN: Thank you.

DR. PICCIONI: Okay. (applause)

ASSEMBLYMAN COLBURN: What I plan to do is call each person who has not testified to just see if I can't get very short information from them, and then, at the end, if there is some question or little rebuttal that anyone would like to give, we will try to accommodate them. That is perhaps evoking a groan from this or that person. Let's see--

UNIDENTIFIED SPEAKER FROM AUDIENCE: Why didn't you finish the witnesses on the front page?

ASSEMBLYMAN COLBURN: I beg your pardon?

UNIDENTIFIED SPEAKER FROM AUDIENCE: Why did you skip Ms. Poch on the front page?

ASSEMBLYMAN COLBURN: Well, to be very honest with you, I was trying to get opinions back and forth, and the scientific people -- to be very candid with you. Now, when you come up with 1000 signatures, or whatever number you might represent-- If you have something, you know, maybe I have been unfair. If I have, believe me, I do apologize. But I am trying to-- The purpose of this hearing is not necessarily to go in the order that people signed in, but to try to get as much information as we can. So, you know, if I flubbed that in some way, I sure-- I know the FDA is fallible, and so am I.

D R. G A R Y C O H E N (speaking from audience): I have a Ph.D. in Chemistry, and--

ASSEMBLYMAN COLBURN: Okay. What is your name?

DR. COHEN: Gary Cohen.

ASSEMBLYMAN COLBURN: Oh, well now, the reason I didn't call the two of you from People for Responsible Management of Radioactive Waste was that I had a feeling that while you might be on the fringes of this hearing, I wasn't sure that we should get into how to dispose of radioactive waste.

DR. COHEN: No, that is not what I am going to speak about.

ASSEMBLYMAN COLBURN: That is not what you are going to say?

DR. COHEN: No.

ASSEMBLYMAN COLBURN: Will you say what you want to say as briefly as you can?

DR. COHEN: Yeah, I won't take long.

ASSEMBLYMAN COLBURN: Okay.

DR. COHEN: I have a lot of material to give you.

ASSEMBLYMAN COLBURN: I know. We got inches and feet of it. This is very thick -- or pretty thick. Are you going to condense this?

DR. COHEN: I don't want to be photographed either. Please turn that off.

ASSEMBLYMAN COLBURN: Okay. Unless a witness agrees to the taping, I would ask that you not do it.

DR. COHEN: I have a Ph.D. in Chemistry from Northwestern University, and worked for four years as a research chemist. I am no longer a chemist. Last year, I submitted a copy of an analysis I did on the FDA's final ruling on the irradiation of fruits and vegetables. I am giving you a copy of that analysis today. In it, I went through their entire ruling and made many, many comments about their position. I have also submitted a letter which I sent to the Secretary of Health and Human Services in Washington concerning food irradiation, and that is fairly technical. You may want to look at that at your leisure. I have also given you, in the back of that package, a couple of pages from a study that the FDA referred to in their ruling of April, 1986.

I am going to make five points about food irradiation:

First of all, in their ruling, they referred to the report, "Recommendations for Evaluating the Safety of Irradiated Foods" -- final report July, 1980 -- which is their theoretical justification for allowing the irradiation of fruits and vegetables. By allowing the irradiationof fruits and vegetables, they permitted virtually all types of plant foods to be irradiated in the United States. That would include grains, beans, vegetables, fruits, seeds, and nuts. This "Recommendations for Evaluating the Safety of Irradiated Foods," if you look at it, there are a couple of references which they used to justify their theoretical calculations. Those two studies which are referred to are for the irradiation

of beef, not for the irradiation of fruits or the irradiation of vegetables.

Now, what the FDA said in their final ruling of last year was the following: "Foods of similar composition will contain by-products that may be viewed in a generic sense." Well, chemically speaking, bananas are not hamburgers, so there is no way you can compare fruits and vegetables to beef. And, yet, they went ahead, just ignoring the fact that they had just claimed you could analyze food generically. They said also that: "Unique radiolytic products, at concentrations of less than one part per million, can be considered safe." I suggest that the FDA should read the studies that they quote.

One of the studies they quote -- and this is one of the beef studies I have here -- is entitled, "Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef." This study -- by the way -- was prepared for the United States Army Medical Research and Development Command. It was prepared by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology. In that study it says: "A more arbitrary guideline is the attempt by some bodies to specify an absolute quantity of a substance as 'toxicologically inconsequential' or 'toxicologically insignificant.' Values of one to ten parts per million in foodstuffs have been suggested by various groups. The Committee believes this 'guideline' to be potentially dangerous for many substances, such as aflatoxins, plutonium, botulinum toxin, dioxin, and others, and are serious health hazards at even lower levels."

So, what they do is, they have studies done, and anything that doesn't sound like it supports food irradiation, they just ignore it, even though it is from a study which supports food irradiation.

Point number three, in the great majority of food irradiation studies, it was the volatile fractions of the foods

that were studied. In other words, what they do is take the food, irradiate it, and then they have to separate out something to analyze. What they do is put it in a flask under vacuum and submit it to high temperature. Those substances that are easily evaporated come off, and they condense them and then they analyze them. What they did was-- They had this group look at the different compounds and, based on toxicological studies, they said, "Well, these substances are not toxic in the amounts present."

What you may not be aware of is that the amounts of material they are analyzing are very, very small, only about 10 parts per million. What this means is, if you take a hamburger and irradiate it, and then you put it in a flask and distill it, you may get one drop of material to analyze.

Now, the volatile components are those components which give the food most of its aroma, and at the same time when you cook it, those are the things that are going to be lost more readily. What is left over is the hamburger, and that is what you eat. It turns out they have done very, very little work studying the nonvolatile components. That is what is left in the flask.

What I suggest is that irradiated foods be labeled, "This food is safe to look at; it may be safe to smell; we are not sure whether it is safe to eat." (laughter and applause) These are very, very simple points, but it seems that no one has noticed them yet. They are very basic.

ASSEMBLYMAN COLBURN: I just wrote that down.

DR. COHEN: Okay. Point number four, a word about labeling. The FDA assures us that the fresh produce sold in bulk will be labeled, if irradiated, in accordance with Chapter 21, Coded Federal Regulations 101.22(e), which applies to labeling of bulk produce that may have applied waxes, oils, or food dyes. There is one problem, though. I have lived in New Jersey for over 15 years, and I have never been in a food store

where this regulation has been obeyed. Furthermore, I have read that the FDA has, in the course of this regulation, done nothing to enforce it. In fact, it is very widely ignored, both in the regular supermarkets and in the national food stores. I read that there are some people out in California who are trying to begin a lawsuit -- a class action lawsuit -- to force the FDA to enforce this regulation. A regulation that is not obeyed or enforced is of absolutely no use to the consumer.

Finally, my fifth point: Irradiated food does not have the same chemical composition as food that has been processed by thermal sterilization or freezing. I have given you a table from the beef study. If you look at it, you will see a column for food irradiated by cobalt-60, one column for food irradiated by electronic accelerator, food that has been thermally sterilized, food that has been cooked, food that has been frozen, and food that has not been treated at all. You will see, going down the columns -- the third and fourth columns -- a lot of zeros for the different chemicals. Okay? If you take a look about two-thirds of the way down on the first page, and then look over to your left at the columns for the irradiated foods, you will see very large numbers. So, you have numbers 500 parts per billion, 700 parts per billion, while if you look under the heading for foods that have been frozen and thermally sterilized, you will see a lot of zeros. There is a really big difference between both types of food.

In this connection, I also have an article, which I did not submit to you, in which it was shown that you can tell whether or not beef has been irradiated through chemical analysis. Its title is, "Detection of Irradiation Treatment of Foods." The authors are W. W. Nawar and J. J. Balboni.

ASSEMBLYMAN COLBURN: Excuse me. On this one (holding up material), is there somewhere here where it is identified where this comes from?

DR. COHEN: No, there isn't.

ASSEMBLYMAN COLBURN: Okay. Well, I think you ought to get that to us. Also, what are you talking about now? I am getting--

DR. COHEN: Okay. It has been said that food that has been cooked--

ASSEMBLYMAN COLBURN: Food that has been irradiated-- You cannot identify what has been irradiated. You are taking issue with that?

DR. COHEN: Yes.

ASSEMBLYMAN COLBURN: Okay. Please, you have to give us your reference on that.

DR. COHEN: This is very interesting, too. I got this reference from one of the major references to--

ASSEMBLYMAN COLBURN: Was it published in a journal, or was it an internal communication, or what?

DR. COHEN: It was published in a journal and, interestingly enough, it is referred to in--

ASSEMBLYMAN COLBURN: I need to have you give it to us in writing, because we are going to get this all discombobulated here unless it is kept in some order.

DR. COHEN: Okay.

ASSEMBLYMAN COLBURN: We need to identify the source of this chart here.

DR. COHEN: Okay. What is interesting about this is, there is a book on radiation chemistry by P. S. Elias and A. J. Cohen, in which they refer to this study. And I said, "Oh, this is very interesting." Of course, I have read that proponents say that irradiated food is not particularly different than food that has been cooked or thermally sterilized. So I went to the library to find the reference, and I couldn't find it. I found the journal, but I couldn't find the reference. There had been no list cited. So, I spent about an hour looking through abstracts, and I finally found

the reference. It turns out that this paper is also referred to in a review article on food irradiation, and the author didn't even bother to go read the article, because they have the same miscitation.

ASSEMBLYMAN COLBURN: He just copied it?

DR. COHEN: Yeah, he just copied it. The abstract is very short, a few sentences. I would like to read it.

ASSEMBLYMAN COLBURN: Well, I'll tell you, I think if you will submit it, we will go over it. I don't think you have to read it.

DR. COHEN: Okay, that's fine.

ASSEMBLYMAN COLBURN: Don't read it, because we've got so many other people here who haven't had a chance. If you would give us copies of that-- I would like to see that.

DR. COHEN: Okay. May I make one point about free choice in the marketplace?

ASSEMBLYMAN COLBURN: No. Free choice in the marketplace -- we've heard that.

DR. COHEN: Well, you have heard it from people who are proponents.

ASSEMBLYMAN COLBURN: Well, I know, but free choice in the marketplace-- What else can you say? Don't say it. I'm sorry, but, you know, really--

You had someone with you -- Veronica Nolan. Veronica, do you have something else to add? I hear you are from my district, so I have to get you-- I just learned that from Bill Naulty, who left.

V E R O N I C A N O L A N (speaking from audience): Well, I am not exactly from your district.

ASSEMBLYMAN COLBURN: Oh, aren't you? In that case-- Bill Naulty is Irish and Nolan is Irish. I guess that is how that worked out.

MS. NOLAN: Actually, Dr. Colburn, I am from Deptford Township.

ASSEMBLYMAN COLBURN: Deptford?

MS. NOLAN: Yes.

ASSEMBLYMAN COLBURN: Riley's district.

MS. NOLAN: I know, yes. By the way, Assemblyman Riley is a cosponsor of A-3150.

ASSEMBLYMAN COLBURN: I wouldn't have mentioned his name.

MS. NOLAN: There are two things I want to say. First of all, for the past year, I have been a regular, ordinary citizen. I am affiliated with the group because it is the group that got me interested in this. But I really spent most of my spare time, and a lot of my not-so-spare time, going around and telling people about food irradiation. It is my experience that nine out of ten people do not know about it. When they first hear it-- They hear it from me for the first time. When they hear about it, they want to know how they can stop it. That has been my experience around the State of New Jersey. Our group has collected over 50,000 letters and signatures.

ASSEMBLYMAN COLBURN: I think we have gotten quite a few ourselves.

MS. NOLAN: You know, it is because of public citizen action. The group's name is just its name, but we are responsible for the people, you know, who got out there and got the thirteenth and fourteenth congressional delegation to cosponsor the Federal bill. It is our effort to get people to write letters, because people care very deeply about this across the State, and I don't think that has been addressed here today -- that the people really do care.

ASSEMBLYMAN COLBURN: And, you know, in a sense I am a politician, as well as a -- I don't know, physician, or whatever I am. We do have to think, naturally, about the voters, but I scheduled this thing because I am trying to figure out what I think is the right thing to do. I know you

have force behind you; that's obvious. But, if there is nothing else to say, you know, except that everyone is interested and everyone is worried, as we are worried about so many things, then I would say, "Keep it short."

MS. NOLAN: Well, it is going to be very short. I just want to reiterate and say that I think that should be a very big priority, regardless of what the scientists are saying.

ASSEMBLYMAN COLBURN: I know, it is very important.

MS. NOLAN: People should not have to have it if they do not want it, clearly. The other thing I wanted to know--

ASSEMBLYMAN COLBURN: Well, if they labeled it, people would not have to buy it.

MS. NOLAN: Well, they will have to buy it, because they won't know. It is already being imported into the country. It is on our shelves, and we don't know it is there now. We need more protection.

The other thing I want to know for myself, and for the people who are here, is, when will this Committee vote on this?

ASSEMBLYMAN COLBURN: Well, a public hearing has to be followed by a period of-- It would not come up before the Committee until after Labor Day. I can assure you of that, because we have a recess coming up. The next meeting of the Health Committee is the eighteenth, and our agenda is set for that.

MS. NOLAN: The eighteenth of what?

ASSEMBLYMAN COLBURN: Of June. Then we have July and August off, so it wouldn't be until after Labor Day.

MS. NOLAN: Well, you know, Dr. Colburn, I want to speak for the people I worked with on this. Please do not let the Assembly and the Senate adjourn before this is heard.

ASSEMBLYMAN COLBURN: Well, they won't adjourn finally; they will adjourn for the summer.

MS. NOLAN: And then there will be the election, and then there will be all the other stuff that can happen which

will get in the way of a vote really being taken on this.

ASSEMBLYMAN COLBURN: Yes, well, all the things that happen. We had a lot of bills all during the year that people feel are very important. I know this one is important, too.

MS. NOLAN: Well, the other thing I want to know, too, very respectfully, is, how come all of us came from all over the State and all of us stayed here all day, and we had people from Washington and people from all over, and we don't have the full Committee to hear the testimony?

ASSEMBLYMAN COLBURN: Well, that is up to the members to answer. I can't answer that. There are two of us here.

MS. NOLAN: I know. You have really been very patient sitting there and everything.

ASSEMBLYMAN COLBURN: I am just trying to learn.

MS. NOLAN: But, it would be really nice if we could have spoken to everyone.

ASSEMBLYMAN COLBURN: I can appreciate that. We will communicate your feelings about that to them.

MS. NOLAN: Thank you.

ASSEMBLYMAN COLBURN: Just a small bit of defense. Mary Messenger is sitting over there representing a couple of the members. She is a staff person. Staff people are very important here. I did want to say that.

Ms. Poch, you have been very patient. Good afternoon -- or, good evening. We'll all have breakfast pretty soon.

L E I L A P O C H: My name is Leila Poch. I am here today representing the Citizens League of Elizabeth, Inc., a civic organization comprised of citizens concerned about the quality of life for people living and working in our city. I am the President. It is my understanding that these hearings are being held because of the concern about food irradiation and the Assembly bill which will ban the sale of irradiated foods in New Jersey.

I do not intend to address this issue from a scientific standpoint. I am not qualified to do so. Instead, I will being to you the perspective of the people -- the concerned people who will be most affected by any and all decisions you, as their elected representatives, might make on their behalf. Don't be misled by our lack of scientific credentials. Since first being alerted to what was about to take place in our city, our organization has spent an extraordinary amount of time learning all we could about food irradiation and the effects the industry could, and would, have on our lives.

Over 18 months ago, a concerned citizen approached our organization and alerted us to the fact that the Port Authority had signed an agreement with Radiation Technology, Inc. to build and lease a food irradiation facility on a site which chey were developing in Elizabeth. Her concerns were centered on the food irradiation process itself, and we agreed to research and find out all we could before taking any action on the matter. I never would have believed then that that meeting would have lead to my appearance before this Committee today.

As the facts about this "newest" of industries associated with the preservation of food unfolded, our membership became more and more alarmed by what we learned. First and foremost, we checked the site and discovered, to our alarm, that it was only hundreds of feet from the runways at Newark International Airport, a fact that no one else seemed to have noted.

Nuclear power plants in the United States are built with tremendously reinforced containment structures. Yet, it is acknowledged that they would not be invulnerable to aircraft impact. It is certain that Radiation Technology Industries did not intend to construct a facility which in any way approaches the structural strength of a reactor containment -- and this one would be built adjacent to a runway!

We learned that three million curies of radioactive material would be housed at the site, and we saw the scene being set for a possible nuclear disaster for the entire metropolitan area. Our fears were confirmed by experts in the field and through a series of public and private information gathering meetings.

We joined other concerned groups to appeal to our elected officials to stop the madness before it was too late. All appeals to the Port Authority itself fell on deaf ears.

Aside from the questionable effects the process may have on the food itself and ultimately those who injest it, we became more immediately alarmed about the location of the facility in our highly populated, heavily trafficked community.

In a world paralyzed by terrorism, we could not understand the logic of locating such a potential danger in the area. What kind of security arrangements are made for all these plants? We were unable to determine any, and that left us with more anxiety.

We must not forget the lessons of Chernobyl. We have yet to determine the long-term damages to health and food chains; they can only be estimated at this point. Through research and articles which appeared in the newspapers, we learned of the accidents, spills, infractions, violations, and unreported leaks that have already occurred at active food irradiation facilities in New Jersey. The safeguards don't seem to be working. How much more damage must our environment suffer?

And, what about the risks in transporting the radioactive material along our highways and city streets? The February 3, 1987 accident of a tractor-trailer truck carrying radioactive material on Route 17 in Ho-Ho-Kus proved that this is a realistic concern. The radioactive material for plants in New Jersey will travel to us from the State of Washington, across the country, placing every community along the route in jeopardy. Are we willing to accept that risk?

Through perserverence and untiring efforts, we were able to convey our fears to our elected representatives, who joined our fight. The Elizabeth City Council not only passed a resolution against locating the plant in Elizabeth, they also passed a resolution in support of adoption of Senate Bills 2571 and 1801, and Assembly Bill 3150. In addition, they visited the Nuclear Regulatory Commission to convey their opposition to the plant. The Union County Board of Chosen Freeholders supported the citizens' concerns and declared the county a nuclear-free zone. While the declaration was overturned in the courts, their action speaks for itself.

Most recently, we brought our concerns to the Federal Aviation Administration because we felt they would have to give approval since the site is near the airspace of Newark International Airport.

While it seems that all of our efforts have been rewarded with the headlines in The Daily Journal of June 10, 1987, stating, "Irradiation Plant is Scratched," the battle is not over. The actions of both houses of the Legislature in Trenton will help in a far greater sense. They will affect what happens in our State from now on. We urge passage of the bill that will halt the sale of irradiated foods in New Jersey.

You must ask yourselves, are all the risks which have been enumerated here today worth the benefit of preserving foods for extra days or weeks? I do not believe we can afford not to spend the time to find out.

I am adding, if you don't mind, that I am interested in learning how Dr. Remmers has been eating irradiated food for some 35 years, since nothing but spices have been available in this country. Where could he possibly be getting it?

DR. REMMERS: I would be very happy to answer that.

MS. POCH: And, also, Dr. Remmers asked, "Why the sudden interest in food irradiation in the past 18 or 24 months? I believe the answer is very simple, Dr. Remmers. We

have just begun to be informed about it, and the more information we gather, the more we oppose it. I would also remind Dr. Remmers that the "we" I am speaking about are the people, not paid lobbyists who are working here in the city for the industry to influence the decision of our legislators. We are just the plain people.

I would like to thank you for allowing me the opportunity to sit here all day, and to speak before your body.

ASSEMBLYMAN COLBURN: We thought it would be late, but, you know, you never know. Thanks a lot. Dr. Remmers, maybe there will be time later on for some of the rest of you to speak. I would rather get to some new material. I know you would be glad to answer that.

Let's see -- Ken Terry, are you still with us here? (affirmative response)

K E N T E R R Y: My name is Ken Terry. I am a resident of Scotch Plains. I am a writer and an editor by profession. I am not a scientist. The group which I represent--

ASSEMBLYMAN COLBURN: You are not a member of the press, are you?

MR. TERRY: You could say I am, but I do not cover this subject area, so don't worry about it.

ASSEMBLYMAN COLBURN: Okay.

MR. TERRY: I write about the music business.

ASSEMBLYMAN COLBURN: Oh, good, all right.

MR. TERRY: The group which I represent -- Citizens United Against the Irradiation Plant -- is a coalition of Union County civic groups, including Union County SANE, the Elizabeth Citizens League -- for which Leila Poch just so eloquently spoke -- and members of the Linden League of Women Voters. We banded together last year to try to prevent the construction in Elizabeth of this plant that Leila has spoken of. Of course, we are very glad that the company has terminated its plans to build the plant. But, I also strongly feel that if this bill

is not passed, the climate may improve for irradiation companies. They may suddenly find that they can get the money to build these plants, and we may be unable to stop them in the future. It was quite a task to even slow them down in this particular case. Not only was the Union County nuclear-free zone overturned in Federal court, but the Port Authority, which owns the land on which the plant was to be built, declined to take an affirmative stand against allowing such use of its site. So, we were up against some big odds. I would hate to see us have to face them again.

Now, opponents of this bill have argued that the Federal government preempts the whole area. If they decide that food irradiation is safe, and they decide these plants are safe with the radioactive material in them, we have nothing to worry about. Well, I think that is just a lot of nonsense. I think the State certainly has a right and a duty to protect the health and welfare of its citizens. Considering the history of Federal regulation and research in this area, I don't believe we can rely on Washington to protect us from the consequences of the bureaucrats' folly.

Now, you have heard about a good number of these consequences during today's hearing, so I will skip quickly over the situation with the food itself. We don't know that it is safe exposing the whole population to this process. Even if only a small percentage -- say 1% -- of the American people were to get cancer as a result, we would be talking about two and a half million people. It is just absolutely ludicrous that in our current state of scientific knowledge we should be allowing this process to go forward.

From an environmental standpoint, the spread of irradiation plants and the transportation activities associated with them, could be absolutely disastrous. To begin with, it would mean a multiplication of the sites at which nuclear materials are now stored. Instead of having, say, five nuclear

power plants in the State, we may have those plants plus another 20 irradiation plants. Each of them, if they are anything at all like the RTI plants in Rockaway or in Salem, would hold two million to three million curies of radioactive material. That is approximately 1000 times as much as you would find in the largest radiation therapy unit in a hospital. That gives you some idea of the magnitude of what we are speaking of. It is so lethal that exposure to the source for one minute will kill you, and almost did kill a worker at RTI's Rockaway plant a few years ago. Another worker in Norway died when he walked into the irradiation chamber of his irradiation plant. That is something I think should be carefully considered, the consequence of -- the possible adverse health aspects to workers.

We also have to think about the safety of millions of people who will be living around these plants. New Jersey is a very heavily populated State, and naturally companies want to build the plants where most of the people live, because this would make transportation of the food back and forth and the shipping so much simpler. If you have large amounts of radioactive material even in heavily shielded areas, you are posing a danger to the surrounding community. I think the history of the plant in Morris County in which radioactive water has actually leaked out into the municipal water supplies is ample testimony to this problem. The fact that the NRC did not discover the situation at International Nutronics until 10 months after it happened, and then only during a routine check, says something about the ability of the NRC to police this area.

I won't go over what Leila said again about, you know, the possibility of an airplane hitting the proposed facility near Elizabeth. I would just like to point out, as far as highway transportation is concerned, that 12% of the cobalt in a facility that uses cobalt must be replenished every year to maintain the strength of the field. This means a lot of

transportation of additional material to the site. The casks used to transport this material on our highways are only one-quarter as massive as those which are required for the radioactive waste from nuclear power plants. Even for those larger casks, they are only designed to withstand 30 mile per hour collision, and a fire of 1500 degrees F. for half an hour. But the average temperature of a highway fire is 1850 degrees, so some chemical fires reach 3000 degrees. A couple of hours duration is not unusual for a fire following a highway accident.

Now, cobalt-60, because it is metallic, cannot be scattered that far and it cannot be dissolved in water. It makes water radioactive through contact. The big problem we are facing if there is a major increase in the number of irradiation plants is that cobalt is in very short supply, and it is very expensive. Therefore, we will facing an infusion of cesium which, in its chloride form, is water soluble, and much easier to get into the environment. Cesium is available in large quantities at military reactor sites, and also at nuclear power plants. As I mentioned in the article that is provided with the copy of my written statement, the Department of Energy is well under way with plans to transfer the cesium to the commercial sector, using food irradiation as a rationale.

Now, this should be very attractive to irradiation operators, becaude DOE is currently using cesium at the rate of eight tenths of a cent per curie per year. By comparison, cobalt-60, with a shorter half life, sells for about $1.00 per curie on the open market. Maintaining cesium supplies at constant radiation strength for 15 years will cost 14 cents per curie, while keeping cobalt emissions at a steady level for 15 years will cost $2.80 per curie. Nevertheless, while the plant operators would save money on cesium, the public would lose. Not only would there be a heightened risk of environmental pollution, but, as in the case of cobalt, local communities

would have to be prepared to shoulder the enormous financial burden of cleaning up irradiation facilities after they are no longer in use. If a company goes out of business and cannot pay to remove the nuclear wastes, a community might be stuck with them. While the DOE would technically still be the owner of the leased cesium, the history of governmental cleanups of radioactive sites does not inspire confidence in their ability to deal with this problem. In the event of an accident at an irradiation plant, the $560 million of compensation allowed under the Price-Anderson Act could fall far short of the economic damages to area businesses and homeowners, plus the medical bills of the affected residents.

Considering all of the negative aspects of food irradiation, one wonders why the government is bothering with it. As was said earlier, despite the banning of certain fumigants and pesticides, irradiation is not required to assure us of an adequate and healthful food supply. There are other methods to kill insects in foodstuffs. Bacteria can be kept to a minimum by proper storage, refrigeration, and canning techniques.

We know the food industry, despite its timidity about coming out and talking about it in public, would like to see the process approved. They would make a lot more money if they had longer shelf life for their food. The government's rationale is not quite so obvious. I don't think the Administration's stated desire to protect public health really comes into play here. Rather, I think the evidence in the public record more amply supports the conclusion that they are trying to dispose of their military reactor wastes, which are very costly to store, and which are currently leaking out of their containers. Ultimately, they would like to reprocess commercial nuclear wastes to procure more plutonium for nuclear weapons. This would provide a convenient rationale.

Basically, we are then left with a shocking breach of duty and morality on the part of the United States government, into which the states, if they are to carry out the mandate of protecting their citizens, must step. I believe the State of New Jersey should be one of the first states to pass legislation banning irradiated food, because its citizens have shown many times that the environment is one of their foremost issues.

Governor Kean recognized this in his last Inaugural Address, when he said, "We know that the continued degradation of our environment will lead inevitably to the ruination of our State, our country, and possibly even our planet. Armed with this knowledge, we have a responsibility to act. If we do not act, then our children will be right to ask: What kind of people were these?"

I should add that in my experience in fighting the irradiation plant in Elizabeth, and working with a lot of concerned citizens around the county, not only did we find that people did not want their food irradiated when they found out about it, but we could not find one single public official -- not one single member of the Board of Freeholders, not one single member of the Elizabeth City Council, or the Newark City Council, or any of our Assemblymen or State Senators from our area, who was willing to come out in public and say, "Wait, wait, we think that irradiating your food is a good idea." Nobody would come out and say that. Why wouldn't they do that? They wouldn't come out and say it because they knew the people were against it. This is a policy which is being transmitted from the top. They are trying to force this on the people. It has nothing to do with what the people want. I think if we are concerned with what the people want, this bill should be passed, and it should be sent up to the Governor for his signature.

Thank you. (applause)

ASSEMBLYMAN COLBURN: I called her name before, and I didn't hear her respond. Is Sister Pat Daly in the audience? (negative response from audience) Okay. Roberta Kopstein? -

R O B E R T A K O P S T E I N: I have a very short statement -- very short.

ASSEMBLYMAN COLBURN: Oh, thank you. We are now on the reverse side of the witness list, although I sure did go out of order plenty.

MS. KOPSTEIN: Chairman Colburn, and members of the Committee: I am Roberta Kopstein, Co-chairperson of the Environmental Task Force of the National Council of Jewish Women, Essex County Section. I would like to read the letter which we sent to all of our State Senators and Assemblymen:

"Dear Representative: On behalf of the Environmental Task Force of the NCJW, Essex County Section, which is comprised of 4300 members, we would like to inform you of our opposition to the FDA's proposals regarding food irradiation. Our concerns involve not only questions of health, but safety factors regarding the transportation of highly radioactive material, security measures within the facilities, and disposal of toxic waste generated.

"We have been conducting an in-depth study of this process for the past 15 months, and have concluded that the data used to justify the large-scale use of food irradiation is insufficient and inconclusive. We sincerely hope that you share our concerns for the health and safety of New Jersey citizens, and that you will support legislation banning this highly controversial process until all aspects of the issue have been properly addressed, and its safety clearly established.

"We welcome your response."

Thank you very much.

ASSEMBLYMAN COLBURN: Thanks a lot. I was going to give Mr. Nestor a chance to speak, because he deferred to

somebody. Is Mr. Nestor still here? (affirmative response) Okay, you will have a chance in a little while. I thought you were saying you didn't want to speak, but maybe you do.

Rebecca Kirschbaum, Environmental Consortium? You will be interested to know that you are number 20 to testify.

R E B E C C A K I R S C H B A U M: A lucky number. Good afternoon. I am Rebecca Kirschbaum, a member of the Steering Committee of the New Jersey Women's Environmental Consortium. I would like to read Report No. One, which is a summary of the preliminary findings of our Food Irradiation Forum.

The New Jersey Women's Environmental Consortium was formed in January, 1986, and is comprised of leaders representing the American Association of University Women, the Junior League, and the National Council of Jewish Women. These individual organizations have a solid history of successfully educating their collective membership of 20,000 New Jersey women, as well as their communities, on a wide range of social issues.

The Consortium is committed to the protection of our natural resources and the judicious use of technology, both of which are essential for the survival of humanity. Citizen participation in forming environmental policy can be increased through education, and can be a strong factor in decisions affecting all of New Jersey.

On November 18, 1986, a Food Irradiation Forum was held at Fairleigh Dickinson University to explore three sets of issues: 1) health questions - loss of nutrition and possible carcinogenic effects; 2) environmental safety in production; and 3) education and the right to know. Every attempt was made to attract to the Forum a diverse group of representatives of the society. Over 500 citizen leaders were identified and invited. One hundred and one attended, and 68 filled out participant response questionnaires.

It was not the purpose of the Consortium to take an opinion poll of the participants, but to utilize their responses, together with video tapes and printed material, in order to develop a policy statement on food irradiation. It was clear from a preliminary review of the structured questions and the participants' responses that the public felt the following:

1) Strongly supports the right of citizens to know when food has been irradiated, both primary flour and produce and secondary restaurant and bakery sources;

2) The public does not feel that watchdog agencies are disseminating sufficient information to the public regarding food irradiation processes and related issues;

3) It is very concerned that studies relating to food irradiation are most inadequate; and,

4) It is concerned about protection of public health during the transportation of source materials, both before and after the utilization in the food irradiation process.

We hope you will take our concerns into consideration when creating New Jersey policy regarding food irradiation.

Thank you for giving us this opportunity to speak.

ASSEMBLYMAN COLBURN: Thanks a lot. How about Harriette Waxman? Is she still here?

H A R R I E T T E W A X (speaking from audience): I am still here. My name is Harriette Wax.

ASSEMBLYMAN COLBURN: I beg your pardon. It says Waxman on our list. We thought you were a relative of Congressman Waxman.

MS. WAX: No, No. Then I am surprised you kept me waiting so long.

ASSEMBLYMAN COLBURN: Oh, I'm sorry. Well, that was on purpose. He is a Democrat. Where are you from, may I ask?

MS. WAX: I am not one of your--

ASSEMBLYMAN COLBURN: No one is my constituent.

MS. WAX: I am from Livingston, New Jersey. My name is Harriette Wax. I was trained as a chemist. I worked for the Chemical Subsidiary of Standard Oil in California, in the Product Development Department. I know how food should be tested before -- not food, but how products are tested in general. I am appalled by what the FDA did in this particular case.

I have many concerns, which you have heard many times today, about the transportation, particularly about hazardous waste. New Jersey has so much of it, we do not need to create more. I hope we don't. I really do hope we don't create any more. Transportation of cesium-137 or cobalt-- In the case of the cobalt-60, Canada-- It only comes from Canada, and they deliver the material here. When it is used up, they will take it back. So, it is transported twice. If they take it back, at least it will not create a hazardous waste site here. However, it is transported twice across our highways. Cesium-137 -- as someone else mentioned -- comes from Hanford, Washington. It is stored in Hanford, Washington, and it has to come all the way across our highways. There have been many, many, many accidents recently which have come to light during the transportation. So, I hope we do not have it.

I am not going to belabor all of the points about all of my concerns about that, but I do want to just bring up a couple of the previous witnesses' statements. One of them mentioned the fact that there is a vitamin change, but it is no more than would be produced by heat. Fine, but the food, in addition to being irradiated, will probably be cooked, so it is losing vitamins twice.

Some of the other things have already been covered by the last gentleman. Then there is the cumulative effect of irradiated foods. If people eat TV dinners, or they travel a lot and eat dinners on airplanes, it will be the chicken or the meat that will be irradiated. It will be the potatoes that

have been irradiated. It will be the piece of bread that has irradiated flour. It will be a lot of foods all in the same TV tray that have been irradiated. We don't know what this is causing, and I say we should stop and know a little bit about it. We should stop and find out a little bit more about it before we go into full-scale production and irradiate food. We just don't know enough about it at this time.

Let's not make the American public-- I lost my notes, so let me just say it. Let's not make the American public guinea pigs. Let it be tested in the laboratories, rather than on the public, so there is not another DES scandal, another Thalidomide, or another asbestos, where you don't find out about it until 20 years down the line.

ASSEMBLYMAN COLBURN: Thank you.

MS. WAX: Also, I have a copy of an article from Jack Anderson -- from the newspaper a year ago -- that I think you might be interested in reading.

ASSEMBLYMAN COLBURN: Yeah, I would like that. Do you want it back? We can make copies.

MS. WAX: No.

ASSEMBLYMAN COLBURN: Thank you.

MS. WAX: You're welcome.

ASSEMBLYMAN COLBURN: James Solakian? (affirmative response) You're still here? You're number 22.

J A M E S R. S O L A K I A N: Thank you. My name is Jim Solakian. I have submitted written testimony -- which I am not going to read -- on behalf of Lois Scheiner, Director of Food Research for Radiation Technology, Inc.

In the interest of time, I would just like to read the last sentence in the written testimony, and then make a few brief comments. The final sentence reads: "Industry and consumers in New Jersey should have a right to the facts on food irradiation, and a right to make an educated choice." I think the word "educated" is very important and very critical

not just to this hearing, but to the whole subject of food irradiation.

I have been involved in business for roughly 25 years, working for a number of Fortune 100 businesses, both in health care and electronics. I worked extensively with many emerging growth companies, especially in the medical technology area. During that time period, many new concepts emerged, terms like -- and I am sure you are familiar with them now -- DNA and cloning. They all came out of the umbrella of genetic engineering. I can distinctly recall when those new concepts came up, almost everyone outside of the industry -- outside of medicine and outside of academia -- were very, very skeptical. This is not an unusual reaction. Most people reject out of hand, without careful analysis, things they do not understand.

A comment came up earlier: "Nine people out of ten don't really understand food irradiation." The natural reaction is to stop it because you do not understand it. Thankfully, genetic technology was allowed to proceed under very close scrutiny. Today, I am sure that most would agree that real progress has been made, and most now are convinced that there is a greater hope of even greater progress in the future.

Now, in the area of food irradiation technology, there are many parallels. It is seeking, in fact, to improve the quality of life. The plants are controlled by Federal regulatory agencies, similar to the control of pharmaceutical plants. The question remains. Many studies have been done. They are mixed studies, and obviously they are confusing. You can hear that from some of the testimony today. Why then is there still-- In the area of food irradiation, why is there still a largely noncommercial technology outside of medical supplies and outside of certain food additives?

I think the answer really is that the industry doesn't have the breadth of management that the pharmaceutical

companies have, and the large health care companies have. They do not have the capital to conduct the broad-based public relations programs that are really necessary to make this technology widely understood, so that the consumer can make an educated choice. This has been a limiting factor, and is one of the reasons we are here today.

Therefore, we look to our legislators to help us to study both sides carefully. The issues, obviously, are complex and very confusing. They will continue to be debated long after A-3150 is either approved or defeated here later on in the session. But, I believe that this technology has passed through very, very many prestigious groups. It has something to offer, both to New Jersey consumers and the national marketplace, and I urge you to give it careful consideration in the ensuing discussions.

Thank you very much.

ASSEMBLYMAN COLBURN: Thank you. Mr. Gene Nestor? Good evening.

E U G E N E N E S T O R: My name is Eugene Nestor. I am Vice President for Regulatory Affairs for Precision Materials Corporation, which is the small irradiation facility in Mine Hill, Morris County, New Jersey. I am a member of the Health Physics Society and am registered with the National Registry of Radiation Protection Technologists. My field of expertise is not the wholesomeness of irradiated foods. My expertise is in the field of radiation protection, and I have been associated in that field for 15 years.

A couple of comments-- I did have a prepared statement, but I don't feel it is necessary at this time. What I would like to state is that the companies in the field are coming out of what I consider the infancy stage. They are now becoming a viable and economic force and, therefore, they can afford to hire people such as myself on a full-time staff basis. My sole duties at Precision Materials Corporation are radiation protection and regulatory compliance.

We have had problems in this industry in the past, but I feel there has been a commitment being made right now by this industry to correct these problems and to move forward into a better position as far as the general public is concerned.

As to your question about how much was released from Chernobyl, it was approximately 17 million curies of cesium-137. As far as a facility having 10 million curies of cesium-137, I should like to point out that these are encapsulated in distinct units of approximately 10,000 curies each, so they are the equivalent of a radiotherapy unit with 8000 to 12,000 curies. These are not one big source of one million curies.

As far as the transportation issue is concerned, 12% per annum replenishment of cobalt-60 is the equivalent of one shipment a year to each facility.

That is all I have to say. Thank you.

ASSEMBLYMAN COLBURN: Thank you. Do you want to ask anything? (directed to Assemblyman Frelinghuysen) (negative response) I think if I need to ask any questions-- I had something in mind but I can't think of it now, so I will let you go. Thank you.

MR. NESTOR: Okay. Thank you.

ASSEMBLYMAN COLBURN: We have one more person who wishes to speak, Barbara Burnham. Good evening.

B A R B A R A A. B U R N H A M: My name is Barbara Burnham. I am President of the National Health Federation Chapter New Jersey. Most of everything I wanted to say has been said. I would just like to say, "Enough already." When we look ahead and see our children -- the projection-- I have eight grandchildren, and half of them can expect to have cancer. Four of my grandchildren are going to have cancer by the year 2000.

I am speaking for myself at this moment, but I know the majority of our members feel the same way. If we can do

anything to protect ourselves from this menace, even if there is just one radiolytic product less in my life -- in my grandchildren's lives-- That is important to me. As Thoreau said, "When you see a man coming at you for the express purpose of doing you good, run for your life," because that is all I have heard, how good this is going to be for us. We don't want it, because we are running and fighting for our lives.

Thank you. (applause)

ASSEMBLYMAN COLBURN: Thank you. Did you want to say something? (addressed to a gentleman in the audience) (affirmative response)

J O H N M A S E F I E L D: My name is John Masefield. I used to be head of development for the Atomic Energy of Canada, currently Chairman of Isomedix, Inc., which has 11 irradiation facilities across North America.

I just want to get a little bit of perspective for everyone's benefit. There are currently about 140 irradiators in the world, predominantly sterilizing medical products. Because this technique of sterilization has long since proven to be the most reliable way of sterilizing single-use medical products -- that is, those medical products that have to be sterilized by a cold method because they are heat sensitive -- the United States embraced this technology to the extent where we now sterilize approximately 50% of all of the single-use medical disposables made in this country with gamma radiation. By far the most prevalent isotope is cobalt-60. The cesium issue -- you will be happy to learn -- will ostensibly become a non-issue. Very little cesium is out there in the field being used industrially, despite the DOE's program, and there is good reason. There was only a finite amount of cesium produced in the days when we thought we would have a nuclear power reactor in every town and we would run out of uranium. So, we separated fission products -- waste fission products -- from the spent fuel rods, and as a result of that we had a supply of cesium.

A long time ago, this country closed down fuel reprocessing plants, and hence there is no available cesium. There are not going to be tens of millions of curies of cesium. There is only one country in the world right now that is reprocessing spent fuel rods, and that is France. Furthermore, it is much less expensive to make the metallic isotope cobalt-60 than it is to contemplate the enormous expense of reprocessing a spent fuel element in order to get cesium.

Therefore, as a result of that, of the 50 million curies of isotopes being used in this country today to safely sterilize medical devices -- medical products -- there are only about three million curies of cesium involved in that whole thing, and that was part of the DOE program.

The future for this technology, therefore, is with the isotope cobalt-60. As Ms. Wax correctly pointed out, 99% of that cobalt-60 comes from the Atomic Energy of Canada, simply because they have heavy water reactors in which there are thermal neutrons, and it is much less costly to produce cobalt-60 in a reactor with thermal neutrons than with the type of nuclear reactor -- power reactor -- that we have built in this country.

So, Canada has a world-wide monopoly on the production of the isotope cobalt-60. They will take back isotope that-- By virtue of the fact that it has been there for maybe two half lives in a facility, maybe 10 years, and you feel it is taking up too much space, they will happily take it back at the time they bring a shipment. They will just send a cask and take it back.

We have no waste disposal problem in this state or any other state in the union as it pertains to the isotope cobalt-60, which is the isotope that is being used so much of the time. So, please keep that in focus.

As for the safe shipment, we have 1000 -- and I may be off in the hundreds; it is either 1400 or 1700 -- cobalt-60 teletherapy units in hospitals around our country. I think we would like to continue to use them. We ship cobalt to those units through your city and town streets all the time. I haven't heard about it in the last 25 years. The casks that have been designed to transship this cobalt have been certified by your own Board of Transport. They meet the very vigorous standards of a 30G force and of sitting in a fire for an hour and a half, and there has never been in the history of transshipment of cobalt-60 a release of radioactive materials from a shipping cask -- a registered shipping cask -- anywhere in the world. That is a worthwhile perspective, considering this has been going on for well over a quarter of a century.

I wanted to add those comments as factors that would perhaps put some of the safety discussion into perspective.

ASSEMBLYMAN COLBURN: So, cobalt-60 is going to be the surviving agent, as opposed to the cesium, in the process?

MR. MASEFIELD: Cobalt-60 has been the predominant isotope from the beginning, and will remain.

ASSEMBLYMAN COLBURN: Cesium is not going to replace it, because there is not enough cesium since they are not making it any more.

MR. MASEFIELD: They are not making cesium and, also, it is really not cost-effective. The only way you can use cesium is if the government chooses to subsidize its use.

UNIDENTIFIED SPEAKER FROM AUDIENCE: That is what they are doing.

ASSEMBLYMAN COLBURN: Wait a minute. Please, folks, come on.

MR. MASEFIELD: The government will subsidize its use through the Department of Energy to encourage the initiation of a program. In other words, to facilitate the development of what they deem to be a very useful process. The government, in

effect, was subsidizing the use of this isotope. The government is not going to subsidize the commercial use of the isotope, no.

ASSEMBLYMAN COLBURN: Cobalt-60 is sent back for reprocessing and concentrating?

MR. MASEFIELD: No, no.

ASSEMBLYMAN COLBURN: No?

MR. MASEFIELD: You take cobalt-59, which we dig out of the ground-- It is primarily used in the alloying of steel. It is a normal element. You bombard it with neutrons, and instead of cobalt-59, which is the natural form, it becomes cobalt-60.

ASSEMBLYMAN COLBURN: Yeah.

MR. MASEFIELD: It then decays to the next stable element in the periodic chart, which is nickel-60.

ASSEMBLYMAN COLBURN: Okay.

MR. MASEFIELD: So gradually what you have-- You have converted a very small percentage of the cobalt-59 atoms in a metal rod into cobalt-60. They then sit and change into nickel-60, and the by-product of that activity is the emission of electromagnetic energy just like light, only one million times the--

ASSEMBLYMAN COLBURN: Say you are using it in a hospital, when your source becomes weak, or not usable, what happens? Does it go back for reprocessing?

MR. MASEFIELD: No, no, it just goes back.

ASSEMBLYMAN COLBURN: Oh, it is sent back. What do they do with it?

MR. MASEFIELD: Well, if you took all of the decayed cobalt-60 that is being produced in the world today, it would fit in a room much smaller than this.

ASSEMBLYMAN COLBURN: I see.

MR. MASEFIELD: We are talking about such minute physical quantities relative to normal hazardous waste concerns, where we talk--

ASSEMBLYMAN COLBURN: And it goes back to Canada, is that what you're saying?

MR. MASEFIELD: Yes, precisely.

ASSEMBLYMAN COLBURN: Okay.

MR. MASEFIELD: It is currently stored at Chalk (phonetic spelling) River, one of their sites.

ASSEMBLYMAN COLBURN: Thanks a lot. You wanted another word, sir? (speaking to someone in the audience)

DR. GIDDINGS: Can you take any more.

ASSEMBLYMAN COLBURN: Yeah, well, I can. I don't know--

DR. GIDDINGS: Thank you very much for the opportunity. There is one key point that I did not emphasize in my haste earlier trying to get through. There appears to be a perception that this technology is being rushed into place, and that we are going off helter-skelter in a big hurry, when prudence should be invoked. The fact of the matter is, this technology -- food irradiation -- was poised to go industrial in the mid-1960s. I lived through that era myself as a graduate student at Michigan State researching it.

Not to go into detail, but what is considered in hindsight to be a very flawed judgment on the part of the Food and Drug Administration in those days -- there are a lot of reasons why that I won't go into-- A moratorium was set off by the U.S. Food and Drug Administration that rapidly spread world-wide in the 1968 to 1970 period. This was to allow an entire new round of safety wholesomeness studies over and above the countless studies that were done up to that point. I mentioned that incomplete bibliography that is one of the appendices. There were over 300 studies by 1966, and they were largely in the U.S. The point I am coming to, obviously, is that we have already gone through a protracted moratorium on industrial food irradiation. The regulatory process and the industrial progress in food irradiation were touched off in

1967-1968 by the FDA. What have an enormous number of additional safety wholesomeness studies done at the national and international levels through the decade of the '70s and beyond, starting in the late '60s-- What have they added to what we already knew in the 1960s, that irradiated foods are safe and wholesome? We went through an entire new cycle of this, at huge expense in manpower and financing and lost opportunities to experience the public health and other benefits of food irradiation. We went through an entire, over a decade long moratorium, and people who are calling for a moratorium now do not appreciate this history because they didn't live through it.

So, enough said on that point. I would like, if I may, to pick up Dr. Piccioni on-- He didn't get all the way into it, but he was part way into -- if I may put it that way -- proposing a study designed that would answer the questions that have to do with concentrated extracts and studying the concentrated extracts of irradiated foods. I would like to invite him to continue on that tack of developing what he believes, because he has academic and other background. Unlike virtually all critics, he does have academic credentials in irradiation processing -- irradiation biology, I should say. I invite him, or challenge him, to fine-tune and cook that research that he feels will ultimately answer the questions which he feels have not been answered yet; namely studies of concentrated extracts and variated foods.

I have a very special reason for requesting that here. This was thoroughly evaluated -- this approach -- back in the '50s and '60s by the best minds at the time in the Food and Drug Administration, the National Academy of Sciences, and various scientific bodies, who got together and agonized over how to do studies to establish the safety wholesomeness of irradiated foods. This is not a new idea. I won't take that thought any further, but I invite him to further develop it, and present it in a final, finished form.

Thank you very much.

ASSEMBLYMAN COLBURN: I guess you two can continue your debate three seconds here and 10 years someplace else. (indiscernible comment or request from Dr. Burnstein, speaking from the audience) Dr. Piccioni?

DR. PICCIONI: First of all, I think I made it fairly clear that I was just saying that some people suggested extraction experiments.

ASSEMBLYMAN COLBURN: I think I asked you a question, and you said that in response to my question.

DR. PICCIONI: There are a lot of problems with them, and I, myself, am actually very skeptical that they are ever going to settle the issue. I think there is a real problem in finding a way to settle this issue -- period.

ASSEMBLYMAN COLBURN: Okay.

DR. PICCIONI: I think it is very basic.

ASSEMBLYMAN COLBURN: Yeah, because you were responding to a question from me.

DR. PICCIONI: Now, there is one thing I would like to bring up about the cobalt, if I may?

ASSEMBLYMAN COLBURN: Go ahead -- briefly.

DR. PICCIONI: Now, you have heard today from the side of people who are saying there are many useful applications for these radiation technologies-- The irradiation of chicken and pork has been mentioned. You should keep in mind that you are talking about irradiating. Anything like a sizable fraction of the total amount of chicken or pork that is sold in this country-- You are talking about the construction of hundreds of these facilities. For example, CH2M Hill, which is a consulting group that works very closely with DOE, has a report in which they say that to irradiate 80% of the pork product in this country would take something like 80 facilities which are of the megacurie size. Now, the AECL -- the Canadian group that provides this cobalt -- has at its disposal a finite

number of these reactors, and they are churning out cobalt. A couple of years ago, they were caught short; they ran out. They were caught short in their ability to supply cobalt-60 to hospitals and their medical sterilization facilities.

ASSEMBLYMAN COLBURN: In a sense, you are saying that by its nature, this process would have to be limited.

DR. PICCIONI: No. On the contrary, I think that I am taking seriously the proposals to expand the applications of this technology to a very large scope, in which case, as CH2M Hill itself as said, it will have to be cesium-137 from the reprocessing of commercial fuel. DOE has testified on this in Congress.

ASSEMBLYMAN COLBURN: Okay. Well, I don't know that we need to go any further with that -- back and forth on that question. Thank you.

Is this your day off from your practice? (addressed to Dr. Burnstein)

DR. BURNSTEIN: No, no, I took the day off, which I have been doing a lot this year. I am not making any money doing it. I am losing a lot, although I have been accused of making a lot of money by some of the people here.

ASSEMBLYMAN COLBURN: Oh, sure. They accuse me of the same thing.

DR. BURNSTEIN: No, I am accused of making money on this process. I must say that I haven't received a penny doing this work. It is just my interest in radiation and health and disease that gets me to do what I am doing.

In commenting on what John Masefield said, and I am happy to meet him, because I read some stuff about him, and read some Nuclear Regulatory Commission statements--

ASSEMBLYMAN COLBURN: I'm sure he is not as bad as you thought.

DR. BURNSTEIN: No, he looks very nice. I like his action, too -- very nice action. I wish I could sound as sophisticated as he does.

ASSEMBLYMAN COLBURN: I think a lot of people who are involved in these controversies are really decent people. I hope you will all remember that, and whatever way I conclude about this, too.

DR. BURNSTEIN: I realize that, too. If I could sound as sophisticated as he does, maybe I would be listened to more often.

ASSEMBLYMAN COLBURN: Okay.

DR. BURNSTEIN: But, first of all, we do have the 77 million curies or so that is being stored that will be used. Secondly, as a physician, please call your hospital x-ray specialist -- call the radiologist in your hospital -- and tell him, "They claim it is safe." The hospitals have been using it. Now, your hospital probably has approximately 4000 curies of cobalt to use for cancer. We are talking about facilities that have 10 to 15 million. When I first heard about this, I called the radiologist in our area about the amount of cobalt in any one facility -- and they were projecting three to ten to fifteen million curies in any one facility-- They just did not believe that that was going to happen, even three million curies. They said, "All we have in Dover General is 4000 curies." That puts a whole different picture on transportation; a whole different picture on safety, etc. They are not in plants like hospitals, where there is a physicist available, and the Regulatory Commission is available. We are checked in a hospital on a weekly basis by the State Board of Health of New Jersey. These plants, the Nuclear Regulatory Commission has told us-- They will have an inspection once every three years, if that often.

On that basis alone, that is where I got started. They say it is perfectly safe. Johns Manville and the others tell you, "Don't worry about cobalt. Cesium is a danger." Cesium will be used. It can be reprocessed. We won't discuss that. Cobalt -- three plants in the State of New Jersey,

okay? The Johns Manville plant had a major accident, where a worker received more radiation than in the history of any other radiation plant in this country -- 400 rads. Five hundred is the lethal dose. The International Neutronics plant, which is in Dover, right near where I live, and where many people live-- Cobalt is never supposed to leak. Well, their water became radioactive. The water leaked throughout the plant, which is the size of this room. The workers came in the next day, and were told to take their badges and put them on their shoulders so they wouldn't register. They swept up the radioactive water, and they poured it down the toilet bowl and they poured it down the shower stall.

For three years, people used a radioactive toilet and a radioactive shower stall. Three years later, two workers blew the whistle. In 1982, the plant was closed up. It took three years to negotiate with the insurance company to do the cleanup in Dover, so for three years we had a radioactive building, shooting radiation out the walls while people were walking around this building. It took three years to negotiate. Three years later, they finally did the cleanup. What happened, as happens every time? It is so expensive that the company went bankrupt. If they were fined, it makes no difference. They were fined, but what happens to the fine? We are paying for the fine; we are paying for the bankruptcy; we are paying for the cleanup.

Has anybody asked you, Dr. Colburn: Has anyone done an epidemiological study of the people in Dover, New Jersey? We were told by Dr. Remmers, "Speak to the people around the plant." Well, go and speak to the people around International Neutronics. Has anybody -- anybody in this State -- done an epidemiological study or asked the people around that community what is happening? We found out during the cleanup that the radioactive water leaked into the ground and migrated a half a block away. People were walking over the radioactive sidewalk

-- or whatever the ground was -- for three years. There is a school a half a block away; there are homes a half a block away. Is anybody interested? Is anybody doing anything? No. That is why we are so interested in stopping this process, because the potential for damage to our genetics and our future is so obvious, that just to irradiate some food, for whatever reason -- which is a totally ridiculous and unncessary process-- There is just too much danger involved. We cannot listen to this flippant type of discussion we heard from the industry people, who were in force here today. "All of us are independent scientists," but they talked about no scientific information. You heard Dr. Louria, an independent, objective, internationally known scientist. Dr. Tritsch -- an independent, objective, free radical researcher in cancer for 25 years -- never got involved in the issue. He was so incensed when he read this, he decided he is going to make a statement in his quiet way, and he has been making a statement.

Dr. Piccioni, and many other scientists we have who are independent, objective scientists, are not in the employ of the industry in any way, and they are totally on our side.

ASSEMBLYMAN COLBURN: Thank you. I am going to cut the hearing off here. What we are going to do is, anything that any of you have heard that you didn't agree with, please send your comments in to us, and we will give them our best attention.

I want to thank you all for lasting this long. We will do our best to come up with the right answers on this difficult problem.

(HEARING CONCLUDED)

APPENDIX

Summary of Testimony
Of
Donald B. Louria, M.D.,
Chairman of Department of Preventive Medicine and
Community Health - New Jersey Medical School
University of Medicine & Dentistry of New Jersey
Newark, New Jersey

June, 1987

I am neither an intransigent opponent of nor an enthusiastic advocate of food irradiation. I think it possible that food irradiation could be a useful technologic advance in the sterilization and preservation of food. Nevertheless, I am today urging that adoption of food irradiation be halted until 2 major issues are resolved.

(1) The issue of safety. It would appear that the FDA gave its approval on the basis of 5 or 6 studies on rats and dogs. These were selected as methodologically sound from a pool of over 2000 studies, over 400 of which appeared potentially good enough for preliminary review. Clearly there are many potential biases in selecting such a small number of studies on which to base major decisions. Supposedly, these are virtually impeccable studies and all the others are deficient.

Two of the studies are in English, 3 in French and 1 in German. The two in English were reviewed by 5 epidemiologists and biostatisticians. Their judgement was that both studies posed substantial problems in interpretation. In one of the two studies, published in 1964, the authors note "consequently, in many cases statistical comparisons were not possible. However, examination of the data intuitively suggests that the differences have no real significance". In actuality, there were differences between controls and those rats given irradiated wheat, but the small numbers of animals may not have permitted statistically significant differences to be found. There were unexplained stillbirths in the litters of rats given wheat irradiated with 20,000 Rads; recalculation of that stillbirth rate shows a significant increase. This study is hardly an endorsement for the safety of irradiating foods.

The other study intensively reviewed has similar problems with statistical significance, unexplained deaths and abnormalities in animals given irradiated foods that are treated dismissively and virtually ignored.

So the 2 studies in English, instead of documenting safety, raise questions about the safety of food irradiation. Additionally, one of the studies suggests that older animals may be more susceptible to adverse effects when eating irradiated foods.

What about the French and German studies? In 2 of the 3 French studies, the dose of radiation to food was less than 50,000 Rads; this small dosage makes the conclusions difficult to apply to the human situation. No specific adverse effects were noted. The German study showed no adverse effects directly, but showed other adverse effects that will be discussed subsequently.

Taken together, these studies could not possibly establish the safety of food irradiation. Indeed, 2 of the studies suggest the technology is not safe.

To the concerns with the very studies the FDA used to document safety must be added a study in India suggesting that malnourished children given irradiated wheat developed chromosomal abnormalities. That study has been severely criticized: and a differently conducted feeding study in China was negative. The acolytes of food irradiation point to criticisms of the Indian study and to the contravening Chinese study to dismiss the potential for chromosomal damage. That is not proper. What is needed is several additional carefully conducted studies that include malnourished children, adequately nourished children and older persons. Until this is done, major questions about safety will persist.

(2) The effects of food irradiation on the nutritional value of food. Two of the animal studies used by the FDA very specifically highlight the food nutrition issue. In the 1964 report in Food and Cosmetic Toxicology, the authors noted that both controls and those fed irradiated wheat were given supplementary vitamins: in part, "this was done to avoid the reproductive difficulties that were attributed to destruction of vitamin E induced by radiation". In the German experiment, in the first year of analysis those animals given irradiated foods weighed significantly less than controls and showed reproductive defects: both these abnormalties were corrected by administration of vitamins, particularly vitamin E.

There are now many other data indicating that irradiation of foods can reduce the nutrient value of those foods. Additionally, further processing of the food, for example by cooking, may result in accelerated nutrient depletion compared to unirradiated foods.

The supporters of food irradiation treat the potential damage to the nutrient value of food as if it were unimportant or nonexistent. That is a major mistake. If the nutrient value of food is reduced, then the argument for food irradiation prolonging shelf life is undercut. Surely, it would not make sense to prolong shelf life if the foods are nutritionally defective.

Until every food is individually tested at variuos conditions of storage, cooking, freezing and thawing, and at various radiation dosages, it would seem to me to be virtually unthinkable to approve food irradiation for general use.

There are other issues of concern:

(1) If there are hundreds or thousands of food irradiation plants throughout the nation, the issue of potential dangers of transportation of radioactive materials must be addressed. Additionally, with a proliferation of plants, there must be real concern about workplace exposure to dangerous radioactive materials. The experience with such plants in New Jersey is not encouraging. The more plants, the less our ability to conduct regular surveillance and therefore the greater the risk of employee dangers due to employer insouciance, oversight or unscrupulous behavior.

(2) It is puzzling that the food irradiation industry is so eager not to label its foods. The plan appears to be to substitute for labeling a symbol that is supposed to inform the consumer the food has been irradiated. They know full well the public will not recognize the symbol or will forget its significance. The industry and the government must agree that if food irradiation is ever adopted, all foods must be prominently labeled so the public can make a clear choice about use of such foods.

(3) Food irradiation is being offered as a means of feeding the world through shelf life prolongation. Before accepting the technology, why is it that no adequate computer modeling has been done to define its potential value? Enough data on undernutrition due to maldistribution of foods, spoilage, rat infestation, political chicanery, etc. are available to permit a computer model that will tell us whether food irradiation is likely to cure 5, 10, 20 or 50 percent of the world undernutrition.

There are 3 final points:

First, if food irradiation is adopted before adequate evaluation of adverse effects is performed, this will result in obfuscation by risk diffusion. That sounds pedantic and confusing. It is not. What it means is simply that once the technology is adopted widely so many people will be exposed to it that it will

be virtually impossible to conduct proper epidemiologic studies on adverse effects because it will be impossible to find an appropriate unexposed population to use as controls.

Second, there should be a very careful assessment of alternate technologies. There is no need for a rush to judgement. It may be that genetic modification of foods can make them pest-resistant and give a longer shelf life. That might be a much better technology for feeding the world.

Finally, this is the kind of issue on which there ought to be a national referendum. Many consumers may not wish to ingest irradiated foods. Since there are other approaches to preventing food-borne infection by proper refrigeration and cooking, many persons may not wish to eat irradiated foods. I believe that governmental and regulatory judgements should take into consideration national wishes about adoption of this technology.

To summarize, I do not believe that irradiated foods have been shown to be safe for general consumption. Equally important, the effects of irradiation on the nutrient contents of food are not established. I cannot conceive that our elected officials will give approval to a technology that may result in the public being asked to consume nutritionally defective foods. I believe the prudent action to take is to prohibit the irradiation of food until the basic issues are sorted out. To do less would be irresponsible.

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I wish to precede my remarks by stating that I do not represent or speak for my employer, the Roswell Park Memorial Institute or the New York State Department of Health. I am speaking as a private citizen, and my opinions are my own, based on 33 years of experience since my doctorate at Cornell Medical College, Rockefeller University, and, since 1959, as a cancer research scientist and biochemist at Roswell Park Memorial Institute.

I am opposed to consuming irradiated food because of the abundant and convincing evidence in the refereed scientific literature, that the condensation products of the free radicals formed during irradiation produce statistically significant increases in carcinogenesis, mutagenesis and cardiovascular disease in animals and man. I will not address the reported destruction of vitamins and other nutrients by irradiation because suitable supplementation of the diet can prevent the development of such potential deficiencies. However, I cannot protect myself from the carcinogenic and other harmful insults to the body placed into the food supply, and I can see no tangible benefit to be traded for the possible increased incidence of malignant disease one to three decades in the future.

Irradiation works by splitting chemical bonds in molecules with high energy beams to form ions and free radicals. When sufficient critical bonds are split in organisms contaminating a food, the organism is killed. Comparable bonds are split in the food. Ions are stable; free radicals contain an unpaired electron and are inherently unstable and therefore reactive. How long free radicals remain in food treated with a given dose of radiation or the reaction products formed in a given food cannot be calculated but must be tested experimentally for each food. Different doses of radiation will produce different amounts and kinds of products.

The kinds of bonds split in a given molecule are governed by statistical consideration Thus, while most molecules of a given fatty acid, for example, may be split in a certain manner, other molecules of the same fatty acid will be split differently (Fig. 1). This is evidenced by the mass spectrum of a compound, which can be used to unequivocally identify that compound by the amounts and kinds of split products (Fig. 2). A free radical can either combine with another free radical to form a stable compound, or it can initiate a chain reaction by reacting with a stable molecule to form another free radical, etc., until the chain is terminated by the reaction of two free radicals to form a stable compound. These reactions continue long after the irradiation procedure. I am bringing this up to give you a rationale for the vast number of new molecules that can be formed from irradiation of a single molecular species, to say nothing of a complicated mixture as a food. Furthermore, the final number and types of new molecules formed will depend on the other molecules present in the sample. Thus, free radicals originating from fats could form new compounds with proteins, nucleic acids, etc. Let me give you an example to appreciate the magnitude of this: It can be calculated that at a dose of 100 k rads (1 K Gray), 6 out of 10^7 (10 million) chemical bonds are broken, an ostensibly small number. Let us look at water, which constitutes about 80% of many foods. Water has 2 bonds. For 100 milliliters (less than ¼ pint) of water, there are 5 gram moles (molecular weight = 18) which equals 10^{25} molecules. If 6 out of 10^7 bonds are broken, then in 100 ml water, 10^{18} bonds are broken. This is a trillion trillion bonds. The hydroxyl radical formed by irradiating water is one of the most reactive entities known

These considerations lead to the following conclusions:

1. A large number of new molecules is formed. Therefore, irradiation is not a process but a means of adding new molecules to food.
2. Theory cannot predict the nature or number or quantity of the new compounds which will vary with the kind of food, the season and location in which it is harvested.
3. Because of the above, extrapolation of the effects of irradiation at one dose to higher doses will not be valid for all molecules, notwithstanding that in several instances, the formation of volatile hydrocarbons from fats has been shown to be related to dose of radiation in a linear fashion.

The fist study I will discuss (1) deals with the danger of irradiation of foods which contain unsaturated fats. This is particularly timely since the American public is being advised to reduce total fat intake, especially intake of saturated fats, because of the excellent correlation between diets high in saturated fats and cardiovascular disease and some forms of cancer. Unsaturated fat consumption is indeed increasing in the United Stes. When polyunsaturated fats are exposed to 1-4 K Grey (100-400 K rads), large concentrations of peroxides are formed and a concomitant oxidation of benzo-pyrenes to mutagenic benzo-pyrene quinones takes place (Fig. 3). This response is dose dependent (Fig. 4). Unsaturated fats as cod liver oil and mackerel oil showed much greater benzo-pyrene quinone formation than saturated fats (coconut oil) or fats containing tocopherol (Vitamin E) as corn oil (Fig. 5). The direct relation between benzo-pyrene quinones and lipid peroxide content is shown in Fig. 6, where the results of irradiation of herring flesh are shown. In summary, this recent study of 1986 clearly shows that peroxidation of lipids by irradiation produces known carcinogens. Not emphasized in this paper is that peroxidation of lipids also results in their cross link polymerization in a manner akin to the drying of oil based paint. These polymers cannot be digested by our digestive enzymes and will likely be deposited as insoluble plaques in blood vessels. This would have analogous results as the deposition of insoluble cholesterol plaques, well known to lead to high blood pressure and cardiovascular disease in some individuals. In a consensus statement frequently quoted to document the safety of irradiated food by proponents of this process (2), the following statement is made on page 17: "In this research, several anomalies appeared in the test animals (for example, hemorrhages, ruptured hearts, and vitamin deficiencies), but these were related to feeding the test animals food they did not customarily eat, and not to treating the foods with ionizing energy". Hemorrhages and rupured hearts bring to mind acute and extremely high elevation of blood pressure I would question the prudence of instigating a study of feeding animals food they do not customarily eat and then dismissing adverse effects for this reason. I do not believe such a statement could appear in the refereed scientific literature.

I would next mention the effects of irradiation on nitrate in foods. Nitrate and nitrite are added to cured meats (bacon, cold cuts, etc.). In addition to inhibiting the growth of some parasites, they impart a desirable pink color to the meats. Irradiation converts nitrate to nitrite in a dose dependent manner (fig. 7). Mutagenesis is directly proportional to nitrite concentration (Fig. 8). Nitrite is a reactive molecule and reacts with nucleic acids and various amino acids in protein and forms the known family of carcinogens known as nitrosamines. These have been unequivocally demonstrated to be potent carcinogens in man (Fig. 9).

Now let me turn to what I believe to be the most convincing and comprehensive group of studies to demonstrate the harmful effects of irradiated food. Some of these studies were performed in man. In 1975 were reported (3) the results of feeding five malnourished Indian children wheat irradiated with 75 K rads. This wheat produced weight gain, serum albumin and hemoglobin levels indistinguishable from what was found with unirradiated wheat. However, 4 of the 5 children showed gross chromosomal polyploidy 4 weeks after initiation of the feeding program.

Chromosome number returned to normal 26 weeks after the feeding was stopped (Fig. 10). This is unequivocal evidence of a potent mutagen in irradiated wheat, so potent in fact that polyploidy was seen in 4 out of 5 children. I would remind you that the high lung cancer incidence in the United States in 1982-1983 was 80 per 100,000, which is equivalent to 0.08 per cent. In these children incidence of polyploidy was 80 per cent.

Let me illustrate the significance of abnormal chromosomes. Fig. 11 shows the normal female chromosomes; Fig. 12 shows the translocation diagnostic for chronic myelocytic leukemia, where a portion of chromosome No. 22 is translocated to the long arm of No. 9. I am showing you this to demonstrate that the translocation of a very small amount of genetic material can have profound and ominous effects. Fig. 13 shows the polyploidy seen in the children fed irradiated wheat. I apologize for the poor quality of this illustration, but one can readily see the abnormal number and shape of the chromosomes. Proponents of food irradiation have attempted to dismiss this study since only 5 individuals were involved, but mercifully no one has repeated this with greater numbers of children, especially since equivalent results were found when irradiated wheat was fed to monkeys (4) and rats (5). In both these studies, polyploidy was seen after several weeks of feeding and returned to normal about 2 months after feeding irradiated wheat was stopped. In summary, I would be hard put to find a group of better studies to demonstrate the mutagenic properties of irradiated wheat.

Earlier studies from the 1960's have shown mutagenesis produced by irradiated sucrose (6,7) in human and carrot cells in culture, even though normal carbohydrate metabolism could be demonstrated (8) in the presence of the irradiated sucrose. This was explained (9) when quantitative analyses were performed: When 280 gram sucrose was irradiated, 263 gram unchanged sucrose was recovered and 0.476 gram formaldehyde and formic acid, and 1 gram of ultra violet absorbing compounds were isolated. The latter would be expected to be formed from multiple condensation reactions from the free radicals produced during irradiation. The mutagenicity of fomaldehyde is well known and is illustrated in Figs. 14 and 15. Table I summarizes these studies with irradiated wheat and irradiated sucrose.

In conclusion, I believe I have presented convincing evidence that irradiation of certain foods can result in mutagen formation within the food. Since carbohydrate is found in virtually all foods and irradiation of sucrose results in mutagen formation, I would submit that irradiation of foods in general should be expected to result in increased mutagen content of foods. Because each food would respond uniquely to irradiation in terms of type and amount of mutagens formed, each food would need to be analyzed in terms of mutagens and carcinogens found in an amount of that food consumed during an average human lifetime. This may be laborious and thus expensive, but is by no means difficult by established and published procedures (10).

TABLE I.

EXPERIMENTAL SYSTEM	DOSE	SUBSTRATE	RESULTS	REFERENCE
Malnourished Children	75,000 r	Wheat	Nutrition OK (weight gain, serum albumin, hematocrit) Polyploidy	C. Bhaskaram and G. Sadasivan, Am. J. Clin. Nutrit. 28:130 (1975).
Rats	75,000 r	Wheat	Polyploidy after 4 wks. feeding	Vijayalaxmi, Int. J. Radiat. Biol. 27:283 (1975).
Monkeys	75,000 r	Wheat	Polyploidy after 4 mo. feeding and 2 mo. after withdrawing	Vijayalaxmi, Toxicol. 9:181 (1978).
Human peripheral lymphs. in culture	2,000,000 rads	2% sucrose	Chromosome breaks and toxicity	M.W. Shaw and E. Hayes, Nature 211:1254 (196
Carrot cells in cult.	2,000,000 rads	sucrose	Chromosome breaks and recombinations	R.D. Holstein, M. Sugii and F.C. Steward, Nature 208:850 (1965).
Carrot cells in cult.	4,000,000 rads	4% sucrose	No effects on carbohydrate metabolism	M. Faust, R.B. Chase and L.M. Massey, Jr., Radiat. Res. 31:201 (1967).
Carrot cells in cult.	4,000,000 rads	280g sucrose (2% soln)	Growth inhibition; 263 g unchanged sucrose + 0.476 g formaldehyde and formic acid + 1 g u.v. absorbing cpds.	F.C. Steward, R.D. Holstein and M. Sugii, Nature 213:178 (1967).
No Experimental Data:	Critique of Steward et al., Nature 208:850 (1965). Chromosome damage in culture has no relation to man Irradiated food is safe; refers to "open literature", but gives no references.			S.A. Goldblith (M.I.T.) Nature 210:433 (1966
No Experimental Data	Critique of Steward et al., Nature 208:850 (1965) Refers to Goldblith above. Additives in irradiated food are largely unknown and will be different for each batch of food Anything mutagenic in any experimental system is potentially dangerous.			G. Löfroth (Sweden), Nature 211:302 (1966).

REFERENCES CITED

1. J.D. Gower and E.D. Wills, "The oxidation of benzo(a)pyrene mediated by lipid peroxidation in irradiated synthetic diets", Int. J. Radiat. Biol. 49:471 (1986).

2. Report No. 109, "Ionizing Energy in Food Processing and Pest Control: I. Wholesomeness of Food Treated with Ionizing Energy", Council for Agricultural Science and Technology, Ames, Iowa. 1986.

3. C. Bhaskaram and G. Sadasivan, "Effects of feeding irradiated wheat to malnourished children", Am. J. Clin. Nutrition 28:130 (1975).

4. Vijayalaxmi, "Cytogenetic studies in monkeys fed irradiated wheat", Toxicology 9:181 (1978).

5. Vijayalaxmi, "Cytogenetic studies in rats fed irradiated wheat", Int. J. Radiat. Biol. 27:283 (1975).

6. M. W. Shaw and E. Hayes, "Effects of irradiated sucrose on the chromosomes of human lymphocytes in vitro", Nature 211:1254 (1966).

7. R.D. Holstein, M. Sugii and F.C. Steward, "Direct and indicrect effects of radiation on plant cells: Their relation to growth and growth induction", Nature 208:850 (1965).

8. M. Faust, B.R. Chase and L.M. Massey, Jr., "Effect of irradiated sucrose on carbohydrate metabolism of carrot cells", Radiation Res. 31:201 (1967).

9. F.C. Steward, R.D. Holsten and M. Sugii, "Direct and indirect effects of radiation: The radiolysis of sugar", Nature 213:178 (1967).

10. L.B. Lave and G.S. Omenn, "Cost-effectiveness of short-term tests for carcinogenicity", Nature 324:29 (1986).

Representative _____
House of Representatives
Washington, DC 20515

Dear Representative,

I am writing in regard to my opposition to food irradiation. I am very concerned about the process, the plant operation, the transportation issues and the damage to food quality. The studies done by the FDA are insufficient, inconclusive and inadequate. I am requesting that you write to Dr. Young of the FDA and Dr. Engle of the US Department of Agriculture inquiring as to why food irradiation regulation was passed even though scientific studies to prove the safety for human consumption are questionable.

I support HR#4762, sponsored by Rep. Bosco from California and cosponsored by 15 of his colleagues. The bill calls for the following;

1. It blocks implementation of the FDA's final rule allowing the irradiation of fruits and vegetables and tripling the amount of radiation that can be used on dried herbs and spices.
2. It blocks the implementation of FDA and FSIS rules which allow the irradiation of pork to control trichinosis.
3. It blocks any further rul s which seek to expand the use of food irradiation.
4. It directs the Secretary of Health and Human Services to, in coordination with the Institute of Medicine of the National Science Foundation, conduct a thorough study of the impact of food irradiation on human health, the environment and transportation safety.
5. It will strengthen existing labeling requirements; require the labeling of irradiated INGREDIENTS; require that irradiated food be labeled immediately and that this be maintained throughout distribution. Insure state and local rights to protect their residents' health.
6. Prohibit the export of irradiated foods that cannot be irradiated in the U.S. (No dumping clause)
7. It requires irradiation facilities to register with the FDA, keep reports on types and amounts of food irradiated and report these activities to the public.

Please support HR#4762 and help keep our quality of health strong for a strong America.

_____
Name

_____
Address

_____

27X

Senator _____
United States Senate
Washington, DC 20510

Dear Senator,

I am writing in regard to my opposition to food irradiation. I an very concerned about the process, the plant operation, the transportation issues and the damage to food quality. The studies done by the FDA are insufficient, inconclusive and inadequate. Please write to Dr. Young of the FDA and Dr. Engle of the US Department of Agriculture inquiring as to why food irradiation regulation was passed even though scientific studies to prove the safety for human consumption are questionable.

Rep. Bosco of California has introduced an excellent bill to provide for further research and protect the health of the public against potential damage from the food irradiation process. There needs to be a companion bill in the Senate to give the same protection that Rep. Bosco's bill provides. I am requesting that you introduce this companion bill after consultation with Rep. Bosco.

_____ _____
Name

_____
Address

- - - cut - along - this - line - - -

Senator _____
United States Senate
Washington, DC 20510

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I am writing in regard to my opposition to food irradiation. I am very concerned about the process, the plant operation, the transportation issues and the damage to food quality. The studies done by the FDA are insufficient, inconclusive and inadequate. Please write to Dr. Young of the FDA and Dr. Engle of the US Department of Agriculture inquiring as to why food irradiatic regulation was passed even though scientific studies to prove the safety for human consumption are questionable.

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_____ _____
Name

_____
Address

ISOMEDIX

TESTIMONY BEFORE THE NEW JERSEY STATE ASSEMBLY HEALTH AND HUMAN RESOURCES COMMITTEE PUBLIC HEARING, JUNE 15, 1987, ON ASSEMBLY BILL NO. 3150 AND SENATE BILL NO. 2571

George G. Giddings, Ph.D.
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11 Apollo Drive
Whippany, NJ 07981

ABSTRACT

By means of this testimony, I hereby submit that if Chapter 5-8 General Food Adulteration - of Title 24 - Food and Drugs is to be amended as proposed by the subject bills, this can only be done in a fair, rational, prudent, responsible and objective manner by doing i in such a way as to preserve the complete harmony and consistency th already exists between it and the matching section 402 of the Federa Food, Drug and Cosmetic Act; namely by defining irradiated foods in terms of "adulterated" something like as follows: "24:5-8. For the purposes of this subtitle food shall be deemed adulterated: A.(7) if has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug and Cosmetic Act.' This phrasing preserves the complete harmony already existing betwee the Federal and State Acts for all of the right reasons, and avoids serious, unjustified departure from consistency with the Federal Act for all of the wrong reasons. Additionally, it preserves the right free choice of the consuming public to knowingly (through product labeling and other information) choose irradiated products if and a they become available, rather than preempting this right of free ch in advance for all of the wrong reasons. Let the informed consumer have the opportunity to 'vote' for-or-against irradiated foods in t marketplace, free from legislated denial of such choices!

INTRODUCTION

My name is George Giddings, I am Director of Food Irradiation Services with Isomedix, Inc., a gamma radiation processing service firm headquartered at Whippany, New Jersey, with eleven plants in the U.S. and Canada primarily servicing the health care products industry. I hold a doctorate in food science and human nutrition, with minor in biochemistry, from Michigan State University. I began my professional career twenty-four years ago this month as a research food technologist with the U.S. National Food Irradiation Program, at the U.S. Army Research and Development Center at Natick, Massachusetts, near my home-town, Boston, immediately following receipt of the Bachelors degree in food science and technology from the University of Massachusetts. I continued food irradiation research while a graduate student and full-time researcher at Michigan State University, and as a member of the Food Science faculty at North Carolina State University where I also taught food chemistry at the senior and graduate levels.

Subsequently, while living over four years in South America with my family, working in agriculture, fisheries and food processing development and technology transfer in general, I provided technical assistance to certain national food irradiation programs in that region. As my family and I were preparing to repatriate back from South America in the Spring of 1981, the Food and Drug Administration formally announced intentions of promulgating its first enabling irradiated foods regulations since the mid-1960's, following the trend being set at the international level, thus breaking an <u>over-a-decade-long moratorium</u> on regulatory and industrial progress while another lengthy round of wholesomeness studies was underway at the national and international levels. It was then that I decided to join the radiation processing industry to help guide and lead this long delayed and awaited progressive regulatory and industrialization phase, and this decision brought my family and I to New Jersey. Destiny called, you might say, and I made this decision in large measure because, through my own first-hand educational training and professional research experience, and that of countless other colleagues in the field, I had long before concluded unequivocally that irradiated foods are safe and wholesome. I and many of my professional colleagues in the field have probably consumed a

greater quantity of irradiated foods over the years in our developmen tal work than the average consumer will ever consume in a lifetime, a my family and I will continue to do so unhesitatingly as they become commercially available, in preference over nonirradiated counterparts where there is a choice.

Besides providing safe and wholesome foods, food irradiation, as it is commonly called, offers proven economic and public health bene- fits to the food and allied industries as well as to the consuming pu lic, and it can help guarantee that certain products either become m available or remain available. These potentials are already being increasingly realized in a growing list of other countries, as evi- denced by the table that constitutes Appendix A of this submission. continue in this vein in the remainder of this testimony, citing spe cific examples and ignoring peripheral nuclear-related and other con founding side issues, which are really what the current contrived co troversy is all about, in order to directly address the letter and spirit of the actual amendment to Chapter 5-8 of the New Jersey Food and Drug Act, Title 24 that is proposed in the subject Assembly and Senate bills, as well as the food safety-related component of the inflammatory rhetoric being used in the promotion of these bills.

Irradiated foods and their raw materials and ingredients have, through painstaking, protracted theoretical and experimental research conducted worldwide for decades, been established as safe and wholesome beyond reasonable doubt to the satisfaction of the overwhelming majority of competent, responsible, knowledgeable and objective scientific bodies and public health/regulatory authorities worldwide. Appendix B of this submission includes a mere sampling of recent documentation that attests to this irrefutable fact. Because of their bulk, full length copies of some of these documents are included in only the master copy of this submission, and are simply listed in the other copies. Inevitably, in a matter of this scope and magnitude with its intrinsic potential for concern arousal and controversy, there are those at this early stage of public awareness and understanding, who predictably and understandably harbor genuine, sincerely felt doubts about food irradiation, but who are open to being convinced through factual information plus their own experience trying irradiated products. This fact has already been amply demonstrated in certain other countries, and already to some extent in the U.S. through actual consumer acceptance tests and survey studies. There are just as predictably those, typically a small but very vocal minority in such matters, including the inevitable handful of contrarian professionals with an 'axe to grind', who firmly defy ever being convinced for a variety of special interest reasons, and who will continue to actively oppose and fight progress no matter what the countervailing evidence. However, this cannot and will not change the irrefutable facts of the matter that are becoming ever more widely appreciated, nor the trend currently underway worldwide, inevitable transitory setbacks notwithstanding. The public needs time to get the facts and make informed choices, and there is no good reason to deny same in this case.

The "jury" may still be out in the arena of public attitudes and perceptions about, and readiness for acceptances of irradiated foods, but the "safe and wholesome beyond reasonable doubt" verdict has most definitely and emphatically been handed down in the scientific and public health arena, and the court of public opinion will eventually follow suit as continuing, stepped-up public informational and educational

efforts as to the true facts of the matter increasingly reach the ge
eral public through the responsible media and other channels. This
not to say that left unimpeded or unobstructed, food irradiation is
the verge of becoming a technological tidal wave engulfing the food
supply with hundreds or thousands of industrial food irradiators dot
ting the landscape by or before the end of this century, or the next
for that matter. I have long felt, and have often said within recen
months and years that industrial food irradiation will continue to
evolve in North America and worldwide in a gradual niche-finding fas
ion, tightly regulated at the national and international levels and
prudently utilized in a selective fashion based upon sound business/
financial, etc., decisions. As with any commercial activity, this i
not to say that the occasional ill-advised business venture can not
take place; but the nature of this technology is such that it simply
does not lend itself, regulatory-wise or otherwise, to deployment ir
loose, helter-skelter fashion. The industrialization of food irradia
tion will be a gradual, evolutionary niche-finding process.

The prudent, rational, gradual niche-finding deployment trend i
already in evidence at the international level, at which it is esti-
mated that between one and two billion pounds of all foods and thei
raw materials and ingredients are currently being irradiated annual
for a variety of purposes. Much of this is radiation disinfestatio
imported grain at the Soviet Black Sea Port of Odessa as an alterna
to chemical insect pest disinfestation methods. One to two billion
pounds sounds like a lot, but it is a relative, but growing, 'drop
the bucket'. The food and allied industries will ultimately decide
when, where and how this technology will be employed in its sector,
just as the health care products industry has been determining same
its sector, and not the radiation processing industry which is basi
cally a service function to user industries. Because one-or-anothe
food irradiation application works wonderfully technically does not
necessarily mean that it will be applied industrially. The economi
and logistics, etc., must also be very favorable. The U.S. food in
try is making its own quiet, in depth evaluation of where, when and
it might make use of food irradiation, vs one-or-another alternativ
most cases, while awaiting completion of the transitory passage of

technology through the arena of public/political debate and contrived controversy, on its way from quiet decades in the research and development arena on into the industrial arena, which it is already increasingly and permanently penetrating worldwide.

In the context of the foregoing, I submit that to enact the letter and spirit of the subject bills; in other words to enact the proposed amendment to the definitions of "adulterated" of Chapter 5-8 of Title 24, the State Food and Drug Act as the amendment presently reads, would be tantamount to taking away, in advance, the right of New Jersey citizens to knowingly and freely choose one-or-another irradiated food per se, or to choose the irradiated product in preference over the non-irradiated counterpart. Further, enactment of this amendment as it presently reads, especially considering the inflammatory rhetoric that has been and continues to be associated with the subject legislation, would be, in effect, preempting this looming right of free choice in an atmosphere of confusion and alarmist obfuscation for all of the wrong reasons. Knowing what I and my professional colleagues know about the true facts of the matter of irradiated food safety, wholesomeness and potential benefit to the consumer, I am confident that if and as food industry sectors decide to make use of the irradiation option for economic, product availability or public health protection reasons, an aware and informed public will knowingly choose the product labeled as having been irradiated for this-or-that purpose if given the choice, just as the spice trade is following the trend established by the health care products industry in gradually changing over from product sterilization with hazardous, toxic ethylene oxide gas to sterilization with clean, reliable, safe, physical ionizing energy. The following examples will illustrate this point.

Like consumers in other states, citizens of New Jersey have been becoming increasingly familiar with and enjoying fruit and produce items imported from many regions that were not available at all even a few short years ago, and this trend continues to grow. In virtually all cases, the U.S. Department of Agriculture and certain State Agriculture Departments such as California and Texas require that the imported product be treated with a post-harvest insect pest control agent as an absolute condition of entry. Use of the traditional post-

harvest chemical fumigation methods, beginning with ethylene dibromic or EDB, formerly the most widely used of these, is being eliminated drastically curtailed for worker safety, air quality and residue reasons. This trend is also a disincentive to the chemical industry to to the effort and expense of developing and registering new chemical pesticides. One-by-one, competing physical methods such as cold-treatment on-board ship of Florida citrus and hot water dipping of Hawaiian papaya have not measured up under commercial/industrial con tions for such reasons as impairment of product quality, low reliabi ity and excessive cost. On all counts, irradiation is increasingly looming as the long-term physical alternative of choice in at least some fruit and produce cases, just as it has become the non-chemical method of choice in the case of 10% of all grain imported into the Soviet Union, as much as 500 thousand metric tons per year of this alone. At the urging of the Hawaii Papaya Industry, the USDA is preparing to finalize the radiation disinfestation treatment schedul that it published in proposed form in the January 5, 1987 Federal Register (Appendix C). Similarly, at the urging of the Florida Citr Industry, the USDA has indicated that it will soon publish a propose radiation disinfestation treatment schedule for Florida citrus so th it can once again be shipped to other U.S. quarantine treatment stat that no longer allow EDB treatment, and eventually to Japan as a cheaper and more reliable alternative to cold treatment on-board sh: in transit. This overall trend is expected to continue, and in the Jersey case it is readily conceivable that an outright ban on the d: tribution and sale of irradiated foods would result in the gradual appearance from supermarket produce sections of at least some impor fruit and produce items that have gained or are gaining popularity here, as well as preemption of additional new fresh fruit and produ items from being introduced. This would be, in effect, taking away right of the fresh fruit and produce industry and the retail grocer trade to offer such products here, and the right of the New Jersey sumer to choose and enjoy them, and for all the wrong reasons.

In 1983, largely in response to the National Pork Producers Council which represents the U.S. pork industry, the Food and Drug Administration approved the irradiation of fresh pork to eliminate

infesting Trichinella spiralis parasites present as a public health threat. This and other earlier approvals were incorporated into the new general FDA irradiated foods regulation that was published in the April 18, 1986 Federal Register (Appendix D; incidentally, the lengthy preamble to this regulation addresses all of the substantive comments filed with the FDA following publication of the proposed rule on February 14, 1984. The challenges that continue to be repeated by anti food irradiation special interest activists are merely the same old addressed and resolved charges 'warmed over', and in some instances, repackaged to appear new to those unfamiliar with what has transpired over the past few years or so). The new, so-called "ELISA test", when adopted by the USDA, will be no more than a somewhat limited diagnostic test for the detection of the presence of the Trichinella spiralis parasite in hog carcasses, and not a means of certifying raw, refrigerated pork as "trichina safe", which the industry wants and needs. Of the only three practical, approved methods of eliminating the parasite as a public health threat in fresh pork; namely cooking, freezing and low-dose irradiation, only irradiation (which the USDA patented in 1921 for this purpose after researching it for several years) leaves the meat in the unaltered, raw fresh form, indistinguishable from the untreated counterpart except for being able to be declared "trichina safe" on labels. It is readily conceivable that one or more pork packers will eventually adopt irradiation and offer "trichina safe irradiated pork" to the public, at least some of whom would likely choose this product for the added security if given the choice. In a similar vein, what with the growth of raw fish and shellfish consumption in restaurants and at home, the U.S. seafood industry and its regulators have become interested in the potential of irradiation to similarly provide security against seafood-borne infectious parasites as well as microbial pathogens, in addition to the traditional interest in extension of fresh market life through spoilage delay. The subject legislation would take away such looming public health-related choices in New Jersey in advance, and for all the wrong reasons.

In recognition of the proven effectiveness of irradiation in reducing or eliminating salmonella and other food-borne microbial pathogens in meat, fishery products and poultry, and in response to

increased media and public awareness and attention given to the unavoidable contamination of poultry, especially, with salmonella and other pathogens, the USDA recently petitioned the FDA for clearance poultry irradiation for salmonella, etc., control (Appendix E; appli tion of which would also result in substantial delay of spoilage, an additional benefit). It is readily conceivable that once this antic pated clearance is in hand one or more fresh poultry packers will ad the technology so as to offer to the public "pathogen free irradiate chicken/turkey", etc. The subject legislation would take away this looming public health-related choice in New Jersey, in advance, and all the wrong reasons. In response to all too frequent food poisoni outbreaks associated with certain fishery products imported frozen f South Asia, and a public outcry in Holland to do something about it, Dutch public health authorities now require such products to be irra ated while frozen to destroy illness-causing path gens before they c go on the market. The Dutch consumer, among others elsewhere, is thereby already benefiting from this proven technology in this publi health context thanks to their enlightened, progressive government.

A final example is the well developed and highly refined metho ogy for producing completely radiation sterilized meal components a complete meals having the same long-term nonrefrigerated storage sta bility as thermally sterilized counterparts, but with proven superi eating quality and nutrient retention. For example, a whole cooked roast, ham or tom turkey can be 'dry-packed' without any juice or o liquid in an impermeable but transparent plastic bag, then radiatio sterilized and stored at ambient temperature for years before being unpackaged and consumed as-is. This decades-long development has s only limited use in U.S. and Soviet manned space flight feeding, an dietary rations for hospital patients with nonfunctional immune sys tems, who are therefore totally vulnerable to any and every infecti The latter include bone marrow transplant and cancer chemo- and rad tion therapy patients, and, more recently, individuals suffering fr acquired immune deficiency syndrome or "AIDS". The latter epidemic given rise to increased interest in such products and their regulat approval, perhaps at first in an "experimental" or "medical foods" text, because of their proven eating quality and nutrient retention

superiority over the thermally sterilized or autoclaved counterpart while providing equal or better assurance of required sterility of the products for such uses. One of only a handful of users of such products in this immune-suppressed patient context is Mrs. Saundra N. Aker, registered dietitian and Director of the Clinical Nutrition Unit of the Fred Hutchinson Cancer Research Center in Seattle. Mrs. Aker has been successfully using a variety of locally prepared radiation sterilized foods with patients there for well over a decade, and she has paid public tribute to the value of these products to her patients on numerous occasions, including a late-1985 segment of the MacNeil-Lehrer News Hour, and the appended article from the July-August, 1984 issue of Nutrition Today (Appendix F). It is readily conceivable that such products will not only gain an FDA "medical foods" clearance, but eventually a general clearance as well whereas they have long been established as not only superior in eating quality and nutrient retention over thermally sterilized counterparts, but safe and wholesome as well. Enactment of the subject proposed legislation/amendment as it is presently worded would, in effect,deny New Jersey medical patients who could similarly benefit by them, and eventually the New Jersey consumer in general the availability of such products within the state in advance, and for all the wrong reasons. One can even stretch ones imagination to envision New Jerseyites at some point having to go out-of-state to purchase such products, just as U.S. citizens occasionally travel abroad to avail themselves of a new drug or treatment because our ultraconservative Food and Drug Administration, which characteristically errs to the side of the public health when harboring the very slightest of doubts, and not vice-versa as some would like to believe, has not yet approved said drug or treatment.

In conclusion, and with the foregoing as prologue I wish to propose what I feel, as a food professional and 'student' of food laws and regulations, to be the most rational, sensible, prudent and reasonable resolution of the current controversy and debate surrounding the subject bills A-3150 and S-2571, or more precisely their proposed amendment to Chapter 5-8 of the State Food and Drug Act, having to do with definitions of adulterated food. As in the case of other state food statutes and regulations, which tend to be patterned after, and in gen-

eral consistency with their federal counterparts for obvious reasons, the subject Chapter is true to this norm of harmony and consistency. Chapter 5-8-A of the State Food and Drug Act, which contains six defi nitions of "adulterated food", is a nearly verbatim replicate of the comparable Section 402-(a) of the Federal Food, Drug and Cosmetic Act which does the same, except that the latter contains seven definitio Definition 402(a)(7) states that "A food shall be deemed to be adulte ated if it has been intentionally subjected to radiation, unless the radiation was in conformity with a regulation or exemption in effect pursuant to Section 409".

Section 409 of the Federal FD&C Act is, of course, the "Food Additives" section which includes the mechanisms through which the F and Drug Administration considers and approves food additives on the basis of established safety and efficacy, in this instance a physica process that was classified as a food additive by the Congress in 19 so that it would be regulated in this fashion. It is in accordance with Section 409, as intended by the Congress, that the FDA promulga regulations approving specific food irradiation applications going a far back as the early-to mid 1960's, and most recently the new gener regulation (Appendix D) finalized in April, 1986. It is in accordar with this section that the FDA is presently considering additional approvals including the irradiation of poultry for pathogen control petitioned for by the USDA.

Clearly, the framers of the State Food and Drug Acts or Statute including in New Jersey, intended that the State Acts be kept as cor sistent as practically feasible with the Federal Act for reasons toc obvious to need mention. There is simply no fact-based reason why defining irradiated foods in terms of adulterated to complete 5-8-A Title 24 by adding the 'missing' clause A(7), so to speak, should depart from this norm; therefore, I submit that if this is to be do the amendment be worded something like as follows: "For the purpos of this subtitle food shall be deemed adulterated: A.(7) if it has been intentionally subjected to radiation, unless the use of the ra tion was in conformity with a regulation or exemption in effect pur suant to section 409 of the Federal Food, Drug and Cosmetic Act", t

preserving the already existing complete consistency and harmony between the two directly related sections.

Now it might be argued that the amendment in its present form in the bills under consideration, if enacted into law, can always be so modified by subsequent amendment if and when deemed appropriate; however I submit that such reasoning in this case would be deeply flawed for at least the following reasons:

As pointed out in earlier sections, serious, objective in-depth examination of the true facts of the matter pertaining directly to defining irradiated foods in terms of adulterated in a statutory context, in isolation from a jumble of confounding peripheral issues and allegations with their accompanying inflammatory rhetoric can only reveal that there is simply no sound reason, based upon irrefutable facts, to go about amending in this 'stepwise' fashion, and every good reason for doing it as I suggest, if it is to be done at all. Merely referring to the "STATEMENT" at the end of the bills as originally submitted bears this out. It refers to "workers exposed to radiation" (as though this were a norm instead of an extremely rare exception) which has nothing whatever to do with defining irradiated foods in terms of "adulterated", and which in New Jersey is infinitely more relevant to gamma irradiation of health care and other nonfood products in any case. The "STATEMENT" also refers to "the impacts associated with the transportation of radioactive material used in the processing" (as though, in the established gamma processing context, there have been any "impacts"), to which the same disclaimers apply. Where it does make reference to actual irradiated food safety the "STATEMENT" makes baseless, and thoroughly refuted and dismissed (by the FDA in Appendix D, for one) inferences about "radiolytic products" possibly causing "cancer, birth defects, or other disorders", and inadequate safety testing, with no indication in the latter instance as to what exactly is felt to be lacking or needed, who is to address it and how, and who is to ultimately review and pass judgment on irradiated food safety, if not the FDA which has already done so.

The amendment, in its present form, in effect calls for yet another lengthy, needless moratorium on regulatory and industrial progress to permit yet more safety research (anti-nuclear backers of

such legislation at the state and federal levels desire no less than the permanent elimination of the entire technology with this approac as but part of a strategy). What is perhaps not fully realized, if all, by those holding this view is that food irradiation is just lat emerging from a needless moratorium which was touched off by the USF in 1967-1968 for much the same reasoning when food irradiation was poised to go industrial then, following already decades of safety te ing that many in the scientific/public health community at that time were convinced had established safety/wholesomeness beyond reasonabl doubt. What did over a decade of additional worldwide safety/ wholesomeness testing during this moratorium accomplish? It merely further confirmed, at great cost in manpower, funds and lost opportu ities to realize the public health and other benefits food irradiati offers, what we in the field at the time well knew; namely that irra ated foods are safe and wholesome, and the process offers many prove potential benefits. Do we need yet another moratorium on long-awai and hard won progress? Put another way, do we need to repeat histo largely to pander to a tiny but noisy activist minority that stands firm defiance of ever becoming convinced of what the mainstream sci tific and public health community has become thoroughly convinced o and thereby deny the majority, who are vaguely aware of the contriv controversy, if at all, their freedom of choice in this context? I no; let the informed New Jersey consumer vote in the supermarket as opportunities for such choices present themselves!

Finally, the subject bills, and especially some of the oral an written statements of their sponsors and outspoken supporters const tute a vote of no confidence in the FDA and its parent Public Healt Service and Health & Human Services Department, whereas the America Medical Assn. and all reputable scientific organizations that have taken a position on the matter in the U.S. have given the FDA a vot confidence. The main criticism heard from this latter side, includ university scientists who have research food irradiation is that th FDA, in its characteristic fashion, is acting much too slowly and ultraconservatively in approving food irradiation applications now it has finally gotten around to doing so, following a years-long m torium of arguable need that it touched off in 1967-68. In comple

its new, general irradiated foods regulations in April, 1986, this unjustly maligned Agency stopped well short of adopting in-toto the Codex Alimentarius International Irradiated Foods Standard that was approved by the World Health Organization and adopted by the U.N. with the approval of this same FDA, which also participated in the development of the Standard over years. Instead, it intends to add additional approvals gradually, on a case-by-case basis.

This is the same FDA that resisted pressure to approve thalidomide in the U.S. twenty-five years ago when it was approved and being used elsewhere, and subsequently resulted in serious birth defects. As a result of this 'close call' the FDA became even more conservative, as evidenced by its setting off a worldwide moratorium on food irradiation regulatory and industrial progress a few years later, the rationale for which has undergone considerable thoughtful criticism, including by t-day's FDA scientists who are dealing with food irradiation in a cautious but positive manner. There are countless other examples of FDA ultraconservatism, as any health care product or food additive manufacturer who has spent a fortune on studies and worked for years to get a product approved can attest. (The latest example of this was the May 29 FDA decision to, at least for-the-time-being, deny approval of a proven effective blood clot-dissolving drug developed by the young biotechnology firm, Genentech, largely over questions as to whether it actually benefits heart attack victims; not because of uncertainty as to its safety. This action sent Genetech's stock plunging and cast a pall over the fledgling biotechnology industry; and the FDA is accused by some of being a pawn of industry). Does <u>this</u> FDA deserve or merit the legislative vote-of-no-confidence that the subject bills and their accompanying alarmist rhetoric demand, essentially to pander to a tiny minority of special interest activists and their converted? This witness is convinced that there is only one rational answer, and it can best be expressed by rejecting the bills outright, or, short of that, by putting right their proposed amendment to Section 5-8 of Title 24 as proposed in this testimony.

Respectfully,

G. G. Giddings

George G. Giddings, Ph.D.

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LIST OF APPENDICES TO TESTIMONY OF

George G. Giddings, Ph.D.
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APPENDIX A: FAO/IAEA Food Irradiation Newsletter Supplement, Apri 1987: List of Irradiated Food Clearances by Country, and Status.

APPENDIX B: (those marked with an asterisk are included in the master set for the Committee only).

1. In Point of Fact: Food Irradiation----World Health Organization, Geneva, 1987.
2. Safety Features of Typical Category IV Cobalt-60 Gamm Irradiators, Nuclear Regulatory Commission.
3. The Microbiological Safety of Irradiated Foods---Worl Health Organization/Food and Agriculture Organizatior 1983.
4. Radiation Preservation of Foods: A Scientific Status Summary by the Institute of Food Technologists Expert Panel on Food Safety and Nutrition. IFT, 1983.
5. Radiolytic Products in Radiation Sterilized Beef, Chicken, Pork, Bacon and Ham---Executive Summary of Final Report by Charles Merritt, Ph.D. et al, 1984. This nearly 500 page report of well over a decade of direct analytical chemical research on radiolytic pro ucts definitively concludes that "<u>There are no unique radiolysis products</u>" (this has since been further sub stantiated at the National Bureau of Standards).
6. Food Irradiation: Technology at a Turning Point--- Chemical & Engineering News, The American Chemical Society, May, 1986 (an in-depth ACS analysis).

* 7. Report of Clinical Research on Human Volunteer Consu of Irradiated Foods in the Peoples Republic of China This most definitive research to date on (lack of) i diated food toxicology employing human subjects, released in 1986, reaffirms that consumption of irra ated foods <u>does not</u> result in sub-chronic clinical m festation such as polyploidy, etc.

* 8. Wholesomeness of Irradiated Food---World Health Organization, 1981 (<u>the</u> definitive WHO document).

* 9. Codex Alimentarius International General Standard fo Irradiated Foods and Code of Practices for the Opera of Radiation Facilities for the Treatment of Foods. FAO/WHO World Food Standards Program, 1984.

*10. Facts on Food Irradiation---National Coalition <u>for</u> F Irradiation, Washington, DC, 1986.

*11. Report on the Safety and Wholesomeness of Irradiated Foods by the British Advisory Committee on Irradiate and Novel Foods, 1986---with comments by the British Medical Association and <u>my</u> rebuttal of the latter nonsense.

*12. Food Irradiation: Prospects for Canadian Technology Development, plus accompanying Discussion Paper--- Science Council of Canada, April, 1987. These documents by this preeminent Canadian Scientific Advisory Council thoroughly refute and repudiate a report of a biased and politicized (on the subject) Committee of the Canadian Parliament on Consumer and Corporate Affairs which was released around the same time and gets all the media play.

*13. Ionizing Energy in Food Processing and Pest Control, 1. Wholesomeness of Food Treated With Ionizing Energy. Council for Agricultural Science and Technology Report No. 109, July, 1986.

APPENDIX C: Use of Irradiation as a Quarantine Treatment for Fresh Fruits of Papaya from Hawaii. USDA Animal & Plant Health Inspection Service Proposed Rule. Federal Register 52 (2):292-295, 1/5/87.

APPENDIX D: Irradiation in the Production, Processing, and Handling of Food; Final Rule - U.S. Food & Drug Administration - Federal Register 51-(75):13376-13399, 4/18/1986.

APPENDIX E: Filing of USDA Food Safety & Inspection Service Food Additive Petition for the Safe Use of Sources of Ionizing Radiation for Reduction of Food-Borne Pathogens (e.g., Salmonella) in Poultry Products. Federal Register 52(34):5343, 2/20/87 (approval expected).

APPENDIX F: On the Cutting Edge of Dietetic Science - Saundra N. Aker, R.D. Nutrition Today, July - August, 1984, pp. 24-27. This article, by the Director of Clinical Nutrition at the Fred Hutchinson Cancer Research Center, Seattle, attests to her excellent results with a variety of radiation sterilized meal components in the diets of her patients since 1974!

APPENDIX G: Symposium on Nutritional and Toxicological Studies on Irradiated Foods: Introductory Remarks. In, Proc. 40th Annual Meeting of the Federation of American Societies of Experimental Biology, Atlantic City, NJ, April, 1956. FEDERATION PROCEEDINGS 15(1) 905- (included to illustrate that such studies have been conducted and evaluated by qualified, competent, knowledgeable and objective learned societies for decades).

APPENDIX H: Wholesomeness of Irradiated Foods: An Annotated Bibliography. Compiled by E.F. Reber, Ph.D. et al, Department of Food and Nutrition, U. of Massachusetts, in, FEDERATION PROCEEDINGS 25(5):1529-79, 1966. (Contains an incomplete list of over 300 entries of published research on irradiated food wholesomeness as of 1966; clearly much had been done by then).

* Irradiation is a physical method of processing foods which is comparable to methods such as heat treatment or freezing. It consists of exposing foods to gamma rays, x-rays or electrons over a limited period of time.

* X-rays and electrons are generated by appropriate machines, while gamma rays are generated by the radionuclides Cobalt-60 and Caesium-137. Cobalt-60 is not a waste product from the nuclear industry but is specifically manufactured for use in radiotherapy, sterilization of medical products and the irradiation of food. Caesium-137 is one of the fission products contained in used fuel rods. It must be extracted in reprocessing plants before it can be used as a radiation source. At present, almost all radiation facilities in the world use Cobalt-60 rather than Caesium-137.

* The irradiation technique has some distinct advantages over conventional food processing methods: foods can be treated after packaging; it permits the conservation of foods in the fresh state; perishable foods can be kept longer without noticable loss of quality; and last but not least, the cost of irradiation and the low energy requirements compare favourably with conventional food processing methods. Irradiation treatment up to the prescribed dose leaves no residue; changes in nutritional value (i.e. loss of some vitamins) are comparable with those produced by other processes and during storage. Foods processed under prescribed conditions for irradiation do not in any way become radioactive - a fact which many people do not understand.

* Food irradiation is not a miracle process which can convert spoiled food into high quality food. It is equally true that not all foodstuffs are suitable for radiation treatment, just as not all foodstuffs are suitable for canning, freezing, drying, etc.

* Food irradiation has two main benefits to the health and wellbeing of man: (a) the destruction of certain food-borne pathogens, thus making the food safer, and (b) prolongation of the shelf-life of food by killing pests and delaying the deterioration process, thus increasing food supply.

* Before introducing this new technology, positive evidence and assurance had to be obtained that it would not have any hazardous side effects. The task of proving this was coordinated by the International Project in the Field of Food Irradiation, in which WHO participated in an observer capacity.

* Data generated by this Project were periodically reviewed by Joint FAO/IAEA/WHO 2/ Expert Committees which represent the collective views of a group of international top-level experts and not just the views of individuals or organizations. In 1980, the conclusion was reached that irradiation of any commodity up to an overall average dose of 10 kGy 3/ presented no toxicological hazard. This Committee also considered that irradiation of food up to this level introduced no special nutritional or microbiological problems, thus establishing the wholesomeness of irradiated food up to an overall average absorbed dose of 10 kGy. No new evidence suggests otherwise.

* In order to respond to questions still existing in 1980 concerning the microbiological safety of irradiated food, the Board of the International Committee on Food Microbiology and Hygiene (ICFMH) of the International Union of Microbiological Societies was approached for a second opinion. The Board analyzed the scientific knowledge to date and concluded that there was no cause for concern; there was no qualitative difference between the kind of mutation induced by ionizing radiation and that induced by other preservation processes, such as heat treatment or vacuum drying. Food irradiation was seen by the Board as an important addition to existing methods of controlling foodborne pathogens and did not, in their view, present any additional hazard to health.

2/ Food and Agriculture Organization; International Atomic Energy Agency; World Health Organization.

3/ The absorbed dose is expressed in terms of the gray (Gy), as recommended by the International Organization for Standardization; k stands for kilo (= 1 000).

* More than 30 countries have recognized the advantages and have given clearance for the use of irradiation in processing some 30 food items and commodities.

* The Joint FAO/WHO Codex Alimentarius Commission 4/ was presented with the conclusions of both the 1980 FAO/IAEA/WHO Expert Committee and the Board of the ICFMH and declared itself satisfied regarding the safety of low and medium dose food irradiation. The Commission adopted the Codex General Standard for Irradiated Food and the Recommended International Code of Practice for the Operation of Radiation Facilities for the Treatment of Food.

* As a result of these internationally agreed documents, all countries - regardless of their stage of development - are encouraged to apply food irradiation. The process not only allows for a larger supply of safe food but also has the advantage of reducing dependence on food treated with chemical substances.

* In order to continue the evaluation of developments in the field of food irradiation, an International Consultative Group on Food Irradiation came into being on 9 May 1984, currently made up of 26 countries 5/ from among Member States of FAO, IAEA and WHO.

* The World Health Organization sees food irradiation as a process which has the potential to increase safe food supplies, thus contributing to primary health care.

* Widespread information campaigns are still required for food irradiation to be fully accepted. WHO is concerned that rejection of the process, essentially based on emotional or ideological influences, may hamper its use in those countries which may benefit the most.

* WHO and FAO are planning a publication on the subject of food irradiation which will discuss the advantages and limitations in comparison with other preservation processes and will outline the benefits for consumers in both developed and developing countries. This publication is expected to appear in 1987.

4/ The Codex Alimentarius Commission is an intergovernmental body implementing the Joint FAO/WHO Food Standards Programme. To date it has a membership of 129 countries.

5/ Argentina, Australia, Bangladesh, Canada, Chile, Egypt, Federal Republic of Germany, France, Hungary, India, Indonesia, Iraq, Israel, Italy, Malaysia, Mexico, Netherlands, New Zealand, Pakistan, Philippines, Poland, Syria, Thailand, Turkey, United States of America, Yugoslavia.

Key for figure 2 with reference to the pertinent part of this standard.

1. Water Cooler 10.4
2. Radiation Room Ventilation System 8.21.2
3. Radiation Room Monitor Probe 8.4
4. Safety Delay Timer Alarms 8.7
5. Emergency Stop Device 8.9
6. Heat and Smoke Sensors 8.20.2
7. Water Level Control—Normal 10.2.1
8. Water Level Control—Abnormal (Low) 10.2.2
9. Source Hoist 8.13
10. 'Source Down' Switch 8.13
11. Roof Plug Interlock Switch(s) 8.15
12. Pool Guard 8.19
13. Radiation Room Shield—Concrete 9.2
14. 'Source Up' Switch 8.14.1
15. Source Storage Pool 9.1
16. Safety Delay Timer Keyswitch 8.7
17. Exhaust Air Intake 8.21.2
18. Personnel and Product Entry/Exit Maze 8.6 & 8.11
19. Radiation Warning Light 8.14.1
20. 'Source Moving' Light 8.14.1
21. Product Entry/Exit Barrier Doors 8.11
22. Product Entry/Exit Maze 8.11
23. Product Exit Monitor 8.12
24. Source Hoist Power Disconnect 8.22
25. Check Source Location 8.3
26. Personnel Access DoorWith Interlocks 8.6
27. Radiation Room Monitor with Alarms 8.4
28. Seismic Detector 8.25.3
29. Master Key Attached to Portable Survey Meter 8.2 & 8.3
30. Control Console 11.1
31. Water Conditioner 10.3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

FRANK E. YOUNG, M.D., PH.D.

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

June 19, 1987

FOR RELEASE ONLY UPON DELIVERY

105-X

Mr. Chairman:

I welcome the opportunity to be here today to testify about the activities of the Food and Drug Administration (FDA) in the area of food irradiation.

Background

Our involvement with irradiation technology to preserve food goes back many years. The possibility that benefits could be derived from irradiated food was explored as early as the late 1930's. It was studied in earnest by the United States government in the 1950's as a potential preservative for military food rations as well as a means of eliminating microorganisms from food, controlling insects, and extending the shelf life of fruits and vegetables under the Atomic Energy Commission's "atoms for peace" program. Although FDA had not yet acquired the specific regulatory authority over the application of this new technology that the Agency possesses today, FDA became involved nonetheless by advocating that wholesomeness testing be conducted before any irradiated foods be marketed or otherwise routinely used.

FDA's involvement in the development of food irradiation became pivotal in 1958, when the Congress mandated in effect, that food irradiation be subject to Federal premarket approval. This involvement was accomplished through a change in the Federal Food, Drug, and Cosmetic Act to prohibit the use of a new food additive until its sponsor established the additive's safety and FDA issued a regulation

specifying its conditions of use. The definition of a food additive was drafted to specifically include sources of radiation intended for use in processing food because this use may affect the characteristics of food.

Since then, FDA has approved food irradiation for five different uses:

- o The first was to control insects in wheat and wheat flour in 1963.
- o The second, in 1964, was to inhibit sprout development in white potatoes.
- o In 1985 FDA approved a third use for food irradiation -- to control the organism that causes trichinosis in pork.
- o The most recent approvals, which occurred simultaneously in 1986, involved two uses. These were:
  - -- to slow growth and ripening and to control insects in fresh fruits and vegetables and
  - -- to kill insects and control microorganisms in dry or dehydrated herbs, spices, seeds, teas and vegetable seasonings.

As I will describe later in my testimony, FDA's principal focus in evaluating each of these uses was to ensure the safety of the irradiated food.

As these approvals indicate, many different technical effects can be accomplished by irradiating food. Irradiation can extend a

product's shelf life by inhibiting the growth and ripening of fresh produce, and by reducing the number of microorganisms that spoil food. Complete sterilization of food by irradiation results in a shelf-stable product similar to canned food. Pathogenic organisms, parasites, and insects found in food can be controlled by irradiation. Additionally, irradiation can change certain physical properties, such as decreasing the rehydration time of dehydrated vegetables, increasing the yield of fruit juice, and tenderizing meat. Other means available for accomplishing the same purposes as the permitted uses in our food irradiation regulations include cooking and chemical treatments.

When food is irradiated, most of the radiation passes through the food without being absorbed. It kills or sexually sterilizes any insects, and prevents fruits or vegetables from ripening too fast thereby extending shelf life. Irradiation leaves no residue in food. It does not make the food radioactive, nor does it pose any danger of radioactivity to consumers. Consumers are not exposed to radiation through handling or ingesting irradiated food.

The ionizing radiation used to accomplish food irradiation can come from various sources, including gamma rays, x-rays and electron beams derived from electron beam accelerators. While radioactive sources that produce gamma rays are currently the most commercially used sources in producing the desired energy levels, these other non-radioactive sources (i.e. electron beams and x-rays) can substitute for them quite well in many instances.

The amount of radiation necessary to treat foods varies depending upon the intended use. Multicell organisms are affected more readily than single cell organisms; growing organisms are affected more readily than dormant organisms. Thus, doses sufficient to slow the ripening process, inhibit sprouts and kill insects would not be enough to kill organisms such as the kind that cause trichinosis. In turn, microbes simpler than trichinella spiralis require a higher dose. Viruses, which are smaller than a biological cell, are very resistant to the effects of radiation.

With a few exceptions for minor dry ingredients, food irradiation permitted by FDA involves technologically low levels of radiation. For example, the amount of radiation necessary to sterilize food is approximately 50 times higher than the amount needed to control insects. It is true, of course, that food irradiation does require levels that are far too high to directly apply to humans, such as the levels used in chest x-rays, for example, but this fact has no bearing on the safety of food for human consumption that is treated with radiation.

A Spectrum of Concerns

Even so, the fact that this process exposes food to ionizing radiation understandably singles it out for more public attention and

concern than most food additives receive. And as with any controversial subject, there is a broad spectrum of views.

On one hand, we have heard expressions of frustration that, in the most technologically advanced country in the world, the full potential of food irradiation is not being met, especially compared with its use in other countries. Many of these concerns have been reflected in recent legislative efforts by Representative Morrison and others to facilitate research and development leading to commercial use as well as enhance public acceptance of food irradiation.

At the other end of the spectrum, some people have expressed the view that all of the safety issues related to food irradiation have not been resolved. These concerns are reflected in legislative efforts by Representative Bosco and others that would repeal some of FDA's approvals of food irradiation and require the National Academy of Sciences to study the risk to human health and the environment presented by the irradiation of food.

I can appreciate both points of view and welcome the opportunity to address these concerns today.

FDA's mission is to determine the safety of the process under specific conditions of use. In summary, I remain convinced that our actions in accomplishing this mission have been scientifically sound. I would characterize our approach over the years as fundamentally cautious and conservative.

We are, perhaps, situated even more toward the cautious end of the spectrum when compared with other nations. The Codex Alimentarius Commission, of the World Health Organization and Food and Agricultural Organization, based on a recommendation of its Joint FAO/IAEA/WHO Expert Committee has reviewed and assessed all data on the wholesomeness of irradiated foods, and has recommended that member nations permit the use of irradiation on food in doses up to 10 times higher than those that FDA has approved.

The Regulation of Food Additives

In carrying out its responsibilities, FDA has followed the same general procedures in the development of regulations for the use of sources of radiation that it follows in the development of regulations for other food additives. Congress' decision to include irradiated food in the food additive provisions of our statute clearly shows that it intended FDA to be responsible for regulating the use of irradiation by requiring a rigorous review of the potential hazards associated with this food treatment process.

As I stated earlier, the burden of demonstrating that a source of radiation can be used safely to irradiate foods was, as with other additives, placed on the proponents of its use. The principal procedure established for premarket approval of an additive's safe use

is the filing of a food additive petition. Such a petition must contain adequate data to demonstrate the safety of the use.

In addition, under the food additive provisions of the act, there is a second procedure by which food additive approvals may come about. The government may, on its own motion, propose to approve a particular set of conditions of use. The evidence supporting the safety of these conditions of use must meet the same standard for demonstrating safety as the evidence in a petition from industry. Generally speaking, the latter procedure is used far less frequently than the petition process. It is generally reserved for circumstances in which the Agency believes that proposing to approve a particular use will be of clear benefit to public health or will allow the Agency to operate more efficiently. In the case of food irradiation, both procedures have been utilized, for reasons that I will explain shortly.

The principal issue associated with the approval of an additive by either procedure is, of course, safety -- and the quality and quantity of scientific evidence needed to establish safety. As with any product or process, it is impossible to prove beyond any doubt that no harm will ever result under any conceivable circumstance. Congress recognized this fact in 1958. In the Committee reports from both Houses on the Food Additives Amendment, Congress said that safety requires proof of a reasonable certainty that no harm will result from the proposed use of any additive.

Food Irradiation and Safety Testing: Early Developments

Since the 1960's, when the first petition for the treatment of food with radiation sources was submitted, the Agency has been confronted with questions about what test procedures are appropriate to establish to a reasonable certainty that no harm will result from the use of radiation sources in the treatment of food.

Traditionally, high dose animal feeding studies are used to determine the safety of a food additive. Such testing requires a determination of the highest "no-effect level" for the tested substance and consideration of the amount of the substance likely to be consumed. To allow for uncertainty in relating data gained from laboratory animals to humans, a 100-fold safety factor is typically applied. In other words, the Agency will not approve human consumption at a level that is any higher than 1 percent of the highest level of consumption of which there was no adverse effect in animals.

Initial efforts by FDA and industry to establish the safety of irradiated foods relied on feeding irradiated food to laboratory animals. In effect, irradiated food was to be tested as if it were a discrete chemical entity similar to a "conventional" food additive. The initial philosophy of the FDA scientists was to develop a core of wholesomeness studies on different types of foods to provide a matrix from which the safety of other foods could be deduced. This approach yielded enough data to permit the Agency in the 1960's to approve

petitions for certain specified uses of ionizing radiation for inspecting food, controlling insect infestation in wheat and wheat flour, and inhibiting sprouting in white potatoes.

Other early petitions did not result in regulations for a variety of reasons. Petitions for the use of radiation for microbial control on citrus fruit, strawberries, fish and fish products, and ham were withdrawn without prejudice because they lacked sufficient data to support the effectiveness or the safety of the process. FDA did not act on other petitions for irradiation of other foods because they were clearly incomplete.

As scientists were discovering, evaluating the safety of irradiated foods by traditional testing methods was impractical for several reasons. The most significant problem was the inability to obtain the 100-fold safety factor. Because the irradiated food itself was considered the substance to be tested in these studies, it was impossible in most instances to feed the exaggerated amounts of food that are necessary for the purpose of traditional toxicological testing.

FDA found that more than half of the petitions that it was receiving on irradiation, as originally presented, did not provide necessary and persuasive evidence to support the requested regulations. As a result, the Agency's Bureau of Science conducted a seminar in 1967 for government scientists and administrators interested in the

processing and review of petitions involving irradiation of food. The seminar presentations were compiled into a report that was used as an aid to evaluation. The 1967 seminar noted the need for more basic research in various disciplines to improve safety evaluation.

Perhaps the low point for food irradiation occurred shortly thereafter, when in 1968 FDA revoked three regulations for irradiating bacon. This revocation reflected a culmination of FDA's concerns about the quality of the safety data being submitted in many irradiated food petitions. When FDA received a petition for irradiating ham that relied heavily on reports originally submitted with respect to bacon, the Agency chose to require submission of the relevant raw data on which the original reports were based. The Agency's reevaluation resulted in FDA concluding that the safety of radiation-preserved bacon had not been sufficiently demonstrated. This conclusion, and resulting revocations, discouraged interest in food irradiation for several years.

Food Irradiation and Safety Testing: An Evolution of Thought

Since 1968, however, scientists have learned much about radiation chemistry of foods, and new scientific data addressing the earlier questions and problems have become available. In the late 1970's, these developments resulted in a renewed interest in irradiation as a possible safe alternative to the use of chemicals in food -- which in turn led FDA to review of the complex issue of irradiated foods. An

internal FDA task force, the Bureau of Foods Irradiated Food Committee, was formed to evaluate the Agency's policy on irradiated foods in light of the then current knowledge in toxicology and radiation chemistry and to recommend criteria for safety evaluation.

The first question confronting the Committee was: what should be tested? Or, more appropriately, what is the difference between an irradiated food and an unirradiated food? The Committee concluded that the only difference of toxicological relevance was the products formed during the irradiation process.

The Committee then asked whether all such products should be of concern, or whether concern should be limited to some smaller portion of these products. Working with data from the U.S. Army's High Protein Food Sterilization Program, the Committee found that of 65 substances produced by irradiation that had been identified by Army scientists, most were also found in cooked meats and in other foods. Only six substances (or about 10 percent) could not be verified in the literature as being present in non-irradiated food, although these six were similar to natural food constituents. The Committee thus concluded that possibly up to 10 percent of all radiolytic products may be unique to irradiated food, although not enough is known about components of nonirradiated foods at such low concentrations to conclude that these 10 percent are indeed unique.

Nonetheless, the Committee decided to assume that unique radiolytic products (URP's) are formed during food irradiation. Based on a considerable body of data on radiation chemistry of foods the Committee then deduced that at an absorbed dose of 1 "kilogray" (kGy) of radiation, about 3 parts per million in a food substance could be unique to irradiated food. Because more than 10 different URP's are likely to be formed, the concentration of any one URP would thus be less than one part per million. The Committee concluded that the chances of a single URP of unusual toxicity being formed in significant amounts at doses below 1 kGy would be negligible, especially since the identified products presumed to be unique are chemically similar to other food components. The Committee also pointed out that its estimates probably overstated the total number of URP's.

The Committee concluded that food irradiated at a dose not exceeding 1 kGy is safe for human consumption and that below this dose, animal feeding tests are not necessary to establish safety. The Committee's finding of safety applied even to a diet where a substantial proportion of the food was irradiated at 1 kGy. Annual feeding and other toxicity tests were recommended, however, for foods irradiated above 1 kGy.

The Committee further concluded that a food that comprises only a small fraction of the human diet (e.g. nutmeg) and that is irradiated at doses up to 50 kGy would necessarily contribute far fewer radiolytic

products to the daily diet than a food representing a significant fraction of the diet irradiated at 1 kGy. Consequently the Committee also recommended that foods comprising no more than 0.01% of the daily diet and irradiated at 50 kGy or less also be considered safe for human consumption without toxicological testing.

As a check on the Committee's findings, FDA's Bureau of Foods established a second team of scientists, the Irradiated Foods Task Group, to review all available toxicological data concerning foods treated with irradiation. The major objectives of this Task Group were to compile and summarize the toxicology data pertaining to irradiated foods, identify any consistencies with respect to adverse findings, look for patterns or trends in results among the studies, and summarize the experimental results at the end of the review. They also tried to determine whether food irradiated at a dose above 1kGy could be considered safe without additional testing, as recommended by Codex Alimentarius. The review involved identifying from FDA files and from open literature all relevant toxicology studies (over 400). The Task Group examined all the studies, paying special consideration to those that appeared to raise questions about adverse effects. The Task Group concluded that studies with irradiated foods had not shown adverse toxicological effects and agreed with the previous Committee's conclusion that there was an adequate margin of safety for foods irradiated below 1 kGy. Hence, the Task Group agreed that toxicology tests on food irradiated at 1 kGy or below are not needed to support

a conclusion that such foods are safe. However, this data base was not adequate to support a broad decision that foods may be irradiated safely at higher doses.

Regulatory Efforts

In March of 1981, FDA announced in the Federal Register the availability of the first Committee's report and invited the public to comment on it. The Agency also stated that it was considering several options, including the possible issuance of regulations on the Commissioner's initiative to permit irradiation of food at doses not exceeding 1 kGy. Such an Agency-initiated regulation would be predicated on the view that since safety had been established at the 1 kGy level, a review of petition after petition for uses within that dose range would be an unnecessary burden and expense to the taxpayers.

Three years later, in February 1984, FDA published a proposal for its cornerstone regulation on food irradiation. Among other things, the Agency proposed to permit the use of irradiation at levels not to exceed 1 kGy for insect disinfestation of food and for the inhibition of growth and maturation of fresh fruits and vegetables. We designed our proposal to assure that no outstanding safety questions remained with regard to four important issues: radioactivity, radiolytic products, nutritional and microbiological concerns.

The Agency simultaneously proposed to permit the use of irradiation at higher doses as well -- 30 kGy -- for microbial disinfection of dried spices and dried vegetable seasonings. This higher dosage level was consistent with the recommendation of the Committee that foods comprising only a small fraction of the human diet could be safely irradiated at 50 kGy. Also, such foods are not sources of nutrients and, being dry, cannot support microbial growth.

In this case, as an additional safety factor, the Agency further noted that because spices are dry, irradiation would likely cause formation of fewer URP's than it would in a moist food. This is because most of the radiolytic products formed in food result from reactions of the hydroxyl radical with other food components -- and water is the primary source of hydroxyl radicals in food.

The Agency did lower the permitted dosage level for spices and seasonings in the proposal to 30 kGy from the 50 kGy that the Committee felt would be safe. FDA is obligated to set a limitation on the levels of use of any food additive substance so that the maximum levels are no higher than reasonably required to accomplish the intended technical effect. In this case, 30 kGy was considered sufficient from an effectiveness standpoint.

The final regulation for these uses was published two years later with only minor modifications. In the interim, FDA approved the use of irradiation not to exceed 1 kGy to kill trichinae in pork based on a petition that it received.

Lingering Misperceptions

Since then, we have discovere nat two common misperceptions have developed about FDA's basis for approving these uses and I am happy to have this opportunity to address them. The first is that the regulations were deficient -- and even illegal -- because they were not based on animal testing, even though the law does not mandate any specific type of test.

We can all agree that there must be sufficient testing to support the conclusion that a reasonable certainty exists that no harm will result from the expected use of an additive. Logically, any test that would not contribute to this conclusion should not be required. FDA has not required animal testing in the past in those situations where, by chemical or other testing and sound reasoning, it could conclude that the use of an additive was safe without animal testing. We are satisfied that low doses and for minor uses of food irradiation, this is the case. Animal testing is simply too insensitive to show an effect from irradiation of food at low doses and, thus, would not contribute additional information to the evaluation of the safety of such uses.

As it turned out, our Task Force's review of the existing toxicological data led to the second misperception -- that the data to support the regulations were inadequate because only five of the 409 studies reviewed by FDA were considered by Agency scientists to be

properly conducted and reported. It is true that most of the reports were inadequate by present-day standards and could not stand alone to support safety. Nonetheless, many contained individual experimental 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.

Further, many of the studies were deemed useful for resolving certain questions. For example, if a potent toxic material were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological signs would be manifest in the studies reviewed. However, Agency scientists saw no consistent patterns or trends of adverse effects that might be attributable to exposure to food irradiated at low dose levels.

Thus, while the annual feeding studies were consistent with a finding that the process is safe, it should also be remembered that FDA did not rely on any of the reports of animal feeding studies as the basis for its regulations. Rather, we relied primarily on data we had on the effect of radiolytic products.

Conclusion

The future of food irradiation will be determined primarily by the actions of consumers and the food industry rather than by FDA. It is important to remember that FDA's responsibility in the evaluation of

food irradiation is limited to the determination of the safety of the process under specific conditions of use. FDA has no proper role as a promoter of a specific food additive or food process. The primary responsibility for such activities remains with industry and consumers who choose irradiated food. In addition, industry's role is to assess the feasibility of this technology and to determine its commercial potential.

Our present posture is to refrain from initiating any more across-the-board rulemaking at dosage levels higher than 1 kGy and to review any petitions that may be submitted to us on a case-by-case basis. At this time, two toxicity considerations prevent the Agency from proposing a general regulation allowing doses up to 10 kGy as recommended by the Codex Alimentarius Standard. First, doses sufficiently above 1 kGy irradiation may be able to retard microbial spoilage without killing all spores of Clostridium botulinum, the pathogen/bacterium that causes botulism. We must ensure that C. botulinum cannot grow and produce a toxin that constitutes a health hazard. If irradiation kills the bacteria that cause the symptoms of spoilage, such as a spoiled odor, but fails to kill all the botulinum spores, a particularly dangerous situation could result. Based on current knowledge, FDA is unable to prescribe generic conditions of irradiation for all foods at all feasible doses to ensure that C. botulinum would not develop and produce toxin without obvious spoilage.

At dosage levels not exceeding 1 kGy there is no such risk because food would spoil in the same manner as nonirradiated food. This is because a dose of 1 kGy or below helps extend shelf life by retarding ripening or sprouting, but is not enough to kill bacteria that cause spoilage.

Second, FDA reviewed a number of animal feeding studies to determine whether foods that are irradiated at doses above 1 kGy could be considered safe without additional toxicological studies. The Agency found this data base, taken alone, is not yet adequate to support a broad decision that all foods may be irradiated safely at higher doses.

Finally, as with any food processing, irradiation can reduce the level of nutrients somewhat, depending on the condition. Based on our earlier review, nutrient loss due to irradiation at doses below 1 kGy appear to be of no dietary significance. FDA has not yet permitted a food that is a good source of vitamins to be irradiated at higher doses. We believe that these should be evaluated on a case-by-case basis.

HISTORY OF FDA ACTIONS ON FOOD IRRADIATION

- February 1963: FDA approved gamma radiation preservation of canned bacon.
- August 1963: FDA approved gamma radiation for control of insect infestation of wheat and wheat products.
- August 1963: FDA approved electron beam radiation for the radiation preservation of canned bacon.
- October 1964: FDA approved gamma radiation for sprout inhibition of white potatoes.
- December 1964: FDA approved X-radiation for the radiation of preservation of canned bacon.
- July 1966: FDA approved electron beam radiation for the control of insect infestation of wheat and wheat products.
- July 1966: FDA approved labeling requirements for food treated by radiation.
- October 1968: FDA rescinded the bacon regulations.
- September 1979: Director, Bureau of Foods established the Irradiated Food Committee to provide a total reassessment of all relevant issues applicable to irradiated foods.
- March 1981: Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption (ANPR) published in the Federal Register.
- Autumn, 1981: FDA offered the opportunity for use of irradiation for insect disinfestation during the California Medfly situation based on certain conditions. However, no firm furnished evidence of meeting these conditions.
- July 1983: FDA approved gamma radiation for microbial decontamination of a specific list of spices and vegetable seasonings.
- February 1984: Proposed rule published in the Federal Register for the use of gamma radiation for sprout inhibition and shelf-life extension of fresh fruits and vegetables, for insect disinfestation of food, and for sterilization of spices.
- June 1984: FDA approved gamma radiation to control insect infestation in garlic powder, onion powder, and certain dried spices.

- April 1985: FDA expanded the specific list of dried spices and vegetable seasoning to include additional herbs, spices, and vegetable seasonings, and blends of these seasonings.

- June 1985: FDA approved gamma radiation to control insect and microbial infestation in certain dried enzyme preparations.

- July 1985: FDA approved gamma radiation treatment of pork to control Trichinella spiralis.

- April 1986: FDA issued final rule approving ionizing radiation for maturation inhibition of fresh food, insect disinfestation of food, and sterilization of spices. The final rule included labeling requirements for both retail and non-retail use, and Current Good Manufacturing Practice (CGMP) provisions. The Agency received objections to the final rule during the objection period.

- February 1987: FDA denied requests for a stay of the regulation for pork (1985) and for the general regulations (1986).

FOODS APPROVED BY FDA FOR IRRADIATION TREATMENT

Food	Purpose	Dose Limit	Date Approved
Fruits and vegetables	To slow growth and ripening and to control insects	Up to 1 kilogray (kGy)	April 18, 1986
Dry or dehydrated herbs, spices, seeds, teas, vegetable seasonings	To kill insects and control microorganisms	Up to 30 kGy	April 18, 1986
Pork	To control *Trichinella spiralis* (the parasite that causes trichinosis)	Minimum 0.3 kGy to maximum of 1 kGy	July 22, 1985
White potatoes	To inhibit sprout development	50 to 150 gray	Aug. 8, 1964
Wheat, wheat flour	To control insects	200 to 500 gray	Aug. 21, 1963

18. Calls on the Commission to submit proposals on comparative and unfair advertising since European rules on misleading advertising are not sufficient to protect consumers from deception, as is shown by the use of the word 'biological' in advertising in the foodstuffs sector;

19. Considers it exceptionally important that European rules on food additives should be clear and easy to use and that this should be an important objective of new European legislation in this matter;

20. Rejects, therefore, the Commission's proposal that food additives should be divided into categories according to their technological function because a given additive theoretically and in practice would certainly have to be included in a large number of specific directives;

21. Calls on the Commission instead to submit a comprehensive directive once the toxicological evaluation is available at the end of next year listing all additives according to type, food, quantity and technical purpose although this does not preclude certain groups of additives being treated together;

22. Regrets that the list of additives is only due to be submitted at the end of next year and calls on the Commission to step up its efforts to respect this time schedule at least;

23. Approves of the scope of application of the Directive but calls on the Council, as a matter of urgency, to adopt the proposals for directives on aromas and extraction solvents in order to complete the scope of legislation on additives;

24. Considers that a flexible procedure for the adaptation and review of rules on additives is particularly necessary, but desires that the Scientific Committee for Food and the Standing Committee on Foodstuffs should not merely be asked to give a toxicological assessment and to establish technological necessity respectively and insists that the European Parliament's scope for control and cooperation should be maintained;

25. Considers that authorization to use additives should be granted sparingly and that the condition of technological necessity should be strictly adhered to;

26. Considers that all proposals for legislation on food additives must have regard to minimizing their use;

27. Considers that the food additive calcium disodium ethylenediaminetetraacetate ($CaNa_2$ EDTA) with antioxidant effect is not necessary because there is no clear technological necessity;

28. Calls on the Commission to adopt the amendments demanded by the European Parliament pursuant to Article 149, second paragraph, of the EEC Treaty and to submit its proposal, thus amended, to the Council;

29. Instructs its President to forward to the Council and Commission, as Parliament's opinion, the Commission's proposals as voted by Parliament and the corresponding resolution.

(d) Doc. A2-216/86

RESOLUTION

on the irradiation of foodstuffs

The European Parliament,

— having regard to the motion for a resolution by Mr Hänsch and others on the irradiation of foodstuffs (Doc. 2-1148/84),

— having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Energy, Research and Technology (Doc. A2-216/86),

A. whereas radiation is used for the industrial conservation of food in several countries of the European Community,

B. whereas West Germany has hitherto banned the irradiation of foodstuffs and the marketing of irradiated foodstuffs,

C. whereas there are still no comprehensive studies of the long-term effects of irradiated foodstuffs on health,

D. whereas the effects of radioactive processing, particularly the loss of nutritional value, arise in addition to the use of chemical substances in agriculture,

E. whereas many doubts still exist about many food products on account of the chemical and natural substances added to them,

F. whereas the European Community is still far from able to guarantee the safety of the products offered to its consumers,

G. whereas limited irradiation of foodstuffs, i.e. limited in time or to specific products, would open the way for the undesirable prospect of irradiation being permitted for all foodstuffs,

H. whereas the WHO report acknowledges that irradiation prolongs the life of perishable foodstuffs without deterioration in their quality and no residue is produced when irradiation is administered at the prescribed dose,

1. Believes that before irradiated foods are freely traded in the Community the Commission must clarify whether it is possible to determine scientifically whether a food or food ingredient has been irradiated and, if so, at what dose;

2. Believes that irradiation can complement traditional methods of conservation and processing;

3. Calls on the Commission to submit a study on methods of conservation which could replace the conservation by irradiation currently in use in the Member States;

4. Believes that if the Commission does propose free trade in irradiated foods, a system of compulsory labelling of such foods must be introduced;

5. Is of the opinion that this system of labelling will have to be made subject to specific rules;

6. Believes that certain shortcomings in the conservation of foodstuffs can be removed more satisfactorily by preventive hygiene than by the use of ionizing radiation;

7. Takes seriously the studies which scientists all over the world have conducted on the subject of ionization;

8. Calls on the Commission to name the scientific findings on which it proposes to base its actions in authorizing the irradiation of foodstuffs;

9. Considers the claim that irradiated foodstuffs have no harmful effects on health to be unproven;

10. Calls on the Commission to specify the methods of detection and analysis that are to make it possible to ensure that a limit is observed where the quantities of added irradiated ingredients fall beneath the scope of mandatory labelling provisions;

11. Rejects on precautionary grounds the general authorization of irradiation as a method of conserving food;

12. Calls on the Commission to give details of the turnover of European undertakings involved in the manufacture, sale and operation of irradiation equipment, as well as of the likely increases in turnover if irradiation is authorized;

13. Calls for a ban on imports of irradiated food and animal feed from non-Member States;

14. Requests that, where irradiation equipment is to be exported to Third World countries, information be provided on the nature of the equipment and the effects of irradiation on foodstuffs; requests in addition that dispatch should proceed only after a declaration of agreement;

15. Calls for support to be given to publicity campaigns to acquaint consumers with the various techniques for conserving food so that they can make informed choices;

16. Calls for informative, clear and unambiguous labelling for all irradiated products from the European Community and third countries to be made mandatory at European level;

17. Instructs its President to forward this resolution to the Commission and the Council.

RECOMMENDATIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

along with the word "irradiated".

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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April 2, 1986
35 Frost Avenue
East Brunswick, N.J. 08816

Gentlemen:

I am enclosing my own letter along with the enclosed letter from People for Responsible Management of Radioactive Waste. As a former research chemist specializing in synthetic organic chemistry (natural products) I was most interested in reading the technical justifications that the FDA has given for permitting some foods to be irradiated as well as for considering further classes of food for irradiation. My analysis below should make it clear that the FDA position is riddled with flaws and is therefore scientifically useless.

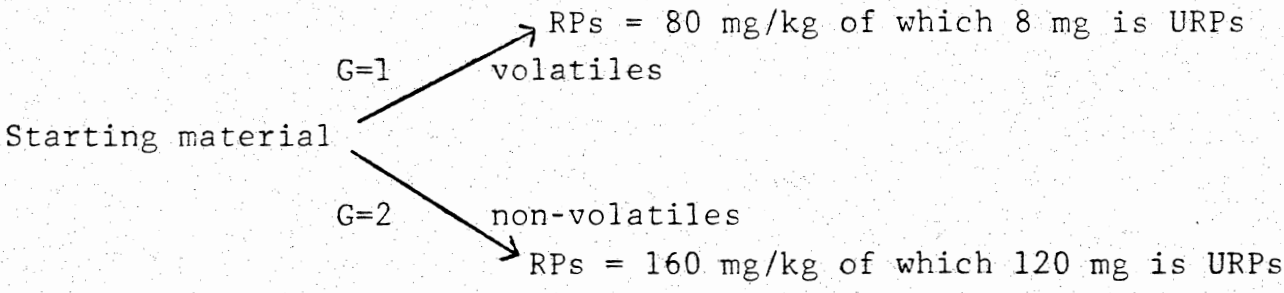
The theoretical basis for the FDA proposed rule (FR 49, No. 31, p. 5714 (2/14/84) was the "Recommendati ns for Evaluating the Safety of Irradiated Foods – Final Report," July 1980, BFIFC [1]. In this Report there is an estimate made for total radiolytic products (RPs) and for unique radiolytic products (URPs) using G-values. "G" is the total number of molecules formed or destroyed per 100 ev absorbed radiation. If one could carry out an experiment where one knows the amounts of all starting materials transformed and all the products formed then the calculated G(destroyed) = G(formed). In an intact food this is clearly impossible because of (1) the complexity of the starting material, (2) the relatively small amounts of products that need to be isolated, and (3) the presence of non-volatiles among the products as well as starting materials. Because of these constraints only the G(formed) for volatile components have been estimated for foods. In the Report a G-value of 1 is used and an RP molecular weight of 300 is assumed. The Report says that "Variations of G_T of plus or minus 100% should not significantly alter the arguments... [1, p. 11]" A major review on food irradiation, which is often quoted by proponents of this process, states "A typical total G-value (depending very much however on the system) would be

3 [2, p. 8]." What the possible significance is of this difference I will elaborate on below. The second problem is the use of MW (molecular weight) = 300 in the calculations. This figure derives from a MW of fatty acids of about 250 in the meat used for irradiation studies. However, this fat is found in the starting material almost totally as triglycerides [2, p. 41] whose MW averages about 800. When the starting fat is split by radiation you will get two or more products whose total molecular weight will be about 800. Therefore, the weight of RP(mg/kg) = RP(mmoles/kg) X MW = Dose(krad) X G_T X 10^{-3} X 800. For 100 krad, G_T = 1 then RP = 80 mg/kg not 30 mg/kg [Cf. 1, pp. 10-12].

Now, what is the significance of the finding of G_T = 1 in irradiated meat but G_T = 3 in many model systems. There are, of course, many possibilities. One is that the G-values are very different in meat than in model systems. If this is the case, then radiation chemistry of model systems is of little value in determining the safety of irradiated foods. These models form the basis for evaluating safety using purely analytical means, otherwise one does not know what to look for in the whole foods. Another possibility is that G_T is actually much more than 1 in irradiated meat, but the bulk of the products are undetected. This is actually quite possible because meat is more than simple fat – there are proteins, nucleic acids, minerals, vitamins, glycogen, etc. It is quite likely that many products would go undetected because they are part of the non-volatile fraction (and analysis was done on the volatile fraction only). If G_T = 3 then the total RPs assuming MW = 800 would be 3 X 80 mg/kg = 240 mg/kg. Because molecular weights for proteins and nucleic acids are usually much more than for fats, the use of MW = 800 is reasonably conservative.

The next question is, what is the proportion of URPs? The Report [1, p. 13] states "... there is no apparent reason to believe that they [volatile fraction] do not also typify the relationship of <u>non-volatile</u> [their emphasis] RPs and URPs

to one another..." It was estimated that only 10% of the radiolytic products are unique (URPs). This assumption of the Report is sheer nonsense. Anyone who has worked as a research chemist should see through this. The reason the products are non-volatile is that they have high MW due to a large number of carbon atoms or they are relatively polar compounds due to the presence of one or more hetero atoms – oxygen, nitrogen, sulfur, phosphorous, etc. The more complex a molecule is the more ways these atoms can be arranged to give isomers. For even relatively small molecules the number of isomers can be astronomical. The probability that even one of these non-volatile products would be found in other foods or in food treated using non-ionizing processing is relatively small. One would be generous to assume 75% URPs in the non-volatiles; it is probably close to 100%. If we assume 10% of URPs from G = 1 and 75% URPs from G = 2 (total G = 3) then we get the following scheme at 100 krads.



The total URPs in this scheme would equal 128 mg/kg. This is over 40 times the estimate in the Report and is based on (1) the actual MW of the starting materials, (2) the actual G-values observed for the volatiles in meat, and (3) a basic understanding of the complexities of high MW non-volatiles.

One more point about URPs. The Report [1, p. 13] says that "enzymatic hydrolysis by digestive enzymes is expected to process the majority of such URPs to yield normal molecular subunits..." I am amazed that such an absurd statement would be made. Of the 65 compounds detected in irradiated beef [3, Table 1, pp. 14-15] not a single product would be degraded by digestive enzymes in the human mouth, stomach, or small intestine.

The human GI tract is designed to degrade carbohydrates, lipids, proteins, and nucleic acids. A look at the 65 compounds reveals that not one falls in any of these categories. Also, the non-volatile fraction would contain many products from carbon-carbon bond formation. These would not be degradable by GI enzymes or for that matter maybe not even by cellular enzyme systems.

In the Report's Policy Recommendations [1, p. 16] it says, "...at this dose [100 krad or less] unique radiolytic products will be on the order of 3 ppm...Hence, because of the low level of total unique radiolytic products produced, it is concluded that food irradiated at doses not exceeding 100 krad is wholesome and safe for human consumption." Please read reference 9, p. 23 of the Report. "A more arbitrary guideline is the attempt by some bodies to specify an absolute quantity of a substance as 'toxicologically inconsequential' or 'toxicologically insignificant.' Values of 1 to 10 parts per million in foodstuffs have been suggested by various groups. The Committee [Life Sciences Research Office, Federation of American Societies for Experimental Biology] believes this 'guideline' to be potentially dangerous [my emphasis], for many substances, such as aflatoxins, plutonium, botulinum toxin, dioxin and others, are serious health hazards at even lower levels [my emphasis] [3, p. 29]."

Finally, the Report [1, p. 11] states, "Thus, foods of similar chemical composition, irradiated under similar conditions, will contain RPs derived from common precursors and such irradiated foods may reasonably be viewed in a generic sense." The Report based its analysis on the irradiation of beef [1, p. 23, Ref. 8 and 9]. FR 49, No. 31, p. 5714 is a proposed rule for the irradiation of vegetables and fruits. A cursory study of the nutritional components of meats vs. vegetables and fruits will show how very different they are. Therefore, the supposition that this Report supports the FDA's proposed rule is total nonsense.

The above analysis is based almost solely on studies and reports by proponents of food irradiation. It should not be construed that there may not be many other problems with irradiated foods. For example, irradiation of fat-containing foods produces

peroxides [2, p. 45ff]. These compounds are chemically highly reactive and may create new products on storage or cooking of the food. Peroxides are widely believed to cause major damage to living cells and thereby contribute to disease and premature aging. Also, the fatty acids present in meat are mainly of the saturated and monounsaturated type. Vegetables, seeds, nuts, and grains have much more of the polyunsaturated type of fats. These latter fats are much more chemically reactive than animal fats and may undergo extensive isomerization or may couple to form oligomers and polymers.

The amino acids in foods are believed to be not much destroyed by ionizing radiation. However, I have not seen any reference to the possible optical isomerization of amino acids in food upon irradiation. Have any experiments been done to detect such possible changes? Humans in general use only the L-isomer of amino acids to synthesize proteins. Most of the amino acids occurring in foodstuffs are of this L-type. If significant quantities of amino acids are converted to the D-isomer (the optical isomer of the L-type) how will that affect the intestinal flora (some bacteria are known to use D- as well as L-amino acids). Will protein be digested as readily if there are D-amino acids present? How might the D-amino acids be absorbed, metabolized, or excreted?

One major review states in connection with polysaccharides, "...although much research has been conducted on the physical and organoleptic properties of irradiated foodstuffs, relatively little work has been carried out on the radiolytic products owing to the complexity of foodstuffs [2, p. 162]." Of course, grains, legumes, and vegetables are principally polysaccharides.

It may be ironic, but the irradiation of plant foods at relatively low dosages (for disinfestation or prolongation of storage) may actually lead to more radiolytic products than at high dosages. At low dosages these foods may undergo extensive genetic mutations without killing a majority of the plant's cells. Because these cells are metabolizing during storage

of the food, but with modified DNA and RNA, the enzymes the cell is producing can be altered along with all the metabolic pathways of a given cell. What this means for the sum total of chemicals produced by the plant is anyone's guess.

Finally, can testing of irradiated foods on animals tell us all we need to know about the safety of this food. What is the effect of irradiated foods on the biochemistry of the human brain and nervous system. If there is an effect, will this lead to an increase in anti-social or criminal behavior.

Sincerely yours,

Mary Cohen

Gary Cohen, Ph.D.

160X

References

[1] Brunetti, A. P., et. al., "Recommendations for Evaluating the Safety of Irradiated Foods," Final Report Prepared for the Director, Bureau of Foods, FDA, July 1980.

[2] Elias, P. S. and A. J. Cohen, "Radiation Chemistry of Major Food Components," Elsevier Scientific Publishing Co., New York, 1977.

[3] Life Sciences Research Office, Federation of American Societies for Experimental Biology. Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef. NTIS, AD-A045716, 1977.

COMMENTS OF GARY COHEN, Ph.D.

ON FINAL REGULATIONS

ON

IRRADIATION IN THE PRODUCTION,

PROCESSING AND HANDLING OF FOOD

FDA DOCKET NO. 81N-0004

MAY 12, 1986

35 Frost Avenue
East Brunswick, N.J 08816
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162X

Comments on Final Regulations on Irradiation
in the Production, Processing, and Handling
of Food, FDA Docket No. 81N-0004

As a consumer of fresh produce I am making the following objections and comments to the final rule concerning the revision of 21 CFR Part 179. My objections are to: (1) the permission to irradiate foods for human consumption and specifically fresh produce because the safety of such consumption has not been adequately established, and (2) the nature of the labeling required, including both the wording and nature of the logo, along with the two-year limitation for the logo. Page numbers below without further citation refer to 51 FR (No. 75, April 18, 1986).

p. 13377 - "...food irradiated at doses up to 1 kGy [100 krad] will have the same nutritional value as similar foods that have not been irradiated."
p. 13381 - "...the available literature indicated that there are no nutritional differences between unirradiated food and food irradiated at levels below 1 kGy [100 krad]."

These statements suggest that FDA is cynically misinforming the American people, or else considers destruction of vitamins in the food to make no difference nutritionally. Some pertinent published statements on this subject are:

"...there is ample published evidence that a number of vitamins are labile to some degree when irradiated. Particular attention should be focused on vitamin A and carotene, vitamin E, vitamin C, vitamin B-12, thiamine, and vitamin B-6 [1, p. II-4]."

"In rolled oats irradiated to 100 krad, tocopherol [vitamin E] retention was 80% initially but fell to 15% after eight months' storage. After the same time period, tocopherol retention in the control sample was 74%. In wheat flour irradiated to 25 krad, retention of thiamine was 80% initially and 33% after three months' storage, at which time it stabilized at this level. In the untreated control thiamine retention was 75% after eight months. Heating

caused further losses that occurred at a greater rate [my emphasis] in the radurized than in the untreated samples [2, p. 452]"

This latter result is ironic, if not shocking, because irradiation is intended to increase the shelf life of the food. The longer these irradiated foods are shelved the less the nutritional value of these foods compared to conventional processing.

"The highest vitamin E losses induced by irradiation occur in food products having a high fat content (Table 8) [3, p. 198]." Examination of Table 8 [3, p. 199] shows a 19% loss of vitamin E for whole nuts irradiated at 100 krad (beta radiation). "In these specific cases, due to the potential high concentration level, the toxicology of the degradation products merit special consideration [3, p. 199]."

These results are of special concern because 50 FR 15415 (April 18, 1985) expanded the list of dried spices and vegetable seasonings in 21 CFR Part 179 to include sesame, poppy and other seeds high in fat. Because the present final regulation has no restrictions on what fresh foods can be irradiated, both seeds and nuts might be treated. This could present both a nutritional problem as well as a toxicological hazard.

p. 13377 - "BFIFC recognized that safety assessments of irradiated food should be based on: (1) Projected levels of human exposure to the foods." A look at Ref. 1, App. III, Table I shows average consumption of different foods in the U.S.A. What about vegetarians who eat little or no animal food of any kind, i.e. meat, poultry, fish, eggs, and dairy? This Table is totally irrelevant to their food consumption, which would be based on grains, vegetables, beans seeds, nuts, and fruit. This regulation assumes minimal consumption of these foods if irradiated. Maybe the labeling requirements should include a statement something like "do not consume this irradiated fresh food, if you are a vegetarian, in amounts more than 40% (or whatever) of your diet!"

p. 13378 - The BFIFC did a theoretical study [1] which concluded

that the radiolytic products (RP's) would be present at 30 ppm, and the unique radiolytic products (URP's) would be present at 3 ppm. These conclusions were based on the volatile RP's from irradiated beef [4 and 5]. When food is cooked it is the volatile materials that are boiled off first. Therefore, what is of most significance is the non-volatile RP's and URP's. These have been little studied. Furthermore, "...foods of similar chemical composition, irradiated under similar conditions, will contain RPs derived from common precursors and such irradiated foods may reasonably be viewed in a generic sense [1, p. 11]." Therefore, what good is a theoretical analysis of the radiolysis products from beef if the present regulation covers fresh foods! Obviously, it's not worth anything. "Hence, because of the low level of total URPs produced, it is concluded that food irradiated at doses not exceeding 100 krad is wholesome and safe for human consumption [1, p. 16]." This conclusion is based in large measure on Ref. 5 which states "A more arbitrary guideline is the attempt by some bodies to specify an absolute quantity of a substance as 'toxicologically inconsequential' or 'toxicologically insignificant.' Values of 1 to 10 parts per million in foodstuffs have been suggested by various groups. The Committee believes this 'guideline' to be potentially dangerous [my emphasis], for many substances, such as aflatoxins, plutonium, botulinum toxin, dioxin and others, are serious health hazards at even lower levels [5, p. 29]."

p. 13379 - "...substances that are chemically similar to radiolytic products are often formed or are present in foods that are not irradiated." So what? This does not make these substances safe to consume.

p. 13380 - "This means the cumulative concentration of all radiolytic products from a pesticide residue would correspond to a concentration of less than 30,000 times smaller than the concentration of the pesticide residue itself." This is totally fatuous nonsense. No competent scientist would make such a stupid statement. Irradiation of beef yields volatile products mostly from the decomposition

of the fatty component of the meat. What happens when a given pesticide is irradiated can only be determined by irradiating it. Its G-value for decomposition may be more or less than that for beef.

p. 13382 - "Such radiation-resistant bacteria, however, would be a problem only if irradiation were essential to produce a safe food. This is not the case and not permitting the use of food irradiation would not prevent such a problem from occurring." If one is eating raw fruits or vegetables that have virulent strains of bacteria, these bacteria could potentially be a serious health problem because raw foods are not processed to kill bacteria.

p. 13384 - "...if a potent toxic material were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological signs would be manifest in the studies reviewed." Why? These studies you reviewed covered a wide variety of foods, tested animals, dosages of radiation used, diets used, etc. One should <u>not</u> expect consistent toxicological signs. On p. 13380 you state "...radiolytic products from different spices are likely to be different." The same is true of different fruits and vegetables, so the toxicological effects would be expected to be different here too. Don't you think so?

p. 13386 - "Such URP's may be free radical coupling products of lipid and protein-derived radicals, dimers, and cross-linked products. However, enzymatic hydrolysis...by normal digestive enzymes is expected to yield normal molecular subunits such as fatty acids amino acids, monosaccharides..." Many of the coupling products may involve carbon-carbon bonds that are <u>not</u> degraded by digestive enzymes. For examples of coupling products see Ref. 6.

Based on the above analysis, it should be clear that the safe of irradiated foods for human consumption has not only not been demonstrated beyond a reasonable doubt but has not been demonstrat to any extent whatsoever. Therefore this regulation should be rescinded until adequate testing and theoretical studies have been completed.

As indicated in the introductory part of these comments, I also object to the requirements for labeling. Prior regulations specified the requirement of a label on retail packages or for bulk produce stating "Treated with ionizing [or gamma or electron] radiation." The new regulation condenses the label to read either "treated with radiation," or "treated by irradiation" [p. 13387]. Furthermore, "The agency has also concluded, however, that the original labeling terminology...may be overly technical and that the type of radiation being used is not necessarily meaningful to the consumers...[p. 13389]" Also, "Recognizing that labeling itself is a valuable source of consumer education FDA encourages optional statements to be included on the retail label that expand upon the kind of treatment used...[p. 13389]"

It is clearly hypocritical of the FDA to say it encourages consumer education but not require it in the form of explicit labels stating that the radiation is ionizing.

Also, "A food is considered misbranded under section 403(a) of the act if its labeling is false or misleading in any particular." "[Labeling is misleading if]...labeling fails to reveal material facts in light of representations made about the food or consequences that may result from the use of such food [51 FR 13390]." Furthermore, "microwave terminology is associated with complete cooking of the food which in no way parallels irradiation treatment of food...[51 FR 13390]" Infrared, ultraviolet, visible as well as microwaves and radio waves are all non-ionizing forms of radiation. Labeling food as treated "by irradiation" or "with radiation" clearly misleads the consumer. He/she will have no idea if the food has been heated with infrared, cooked with microwaves, or treated with gamma rays.

p. 13390 - "The agency is of the opinion that it is in the public interest for labels to bear a statement that is as descriptive of the process as possible." Now is a good time to practice what you preach. Please go back to the former labeling requirements.

I also object to the two-year limitation on the wording requirement. If irradiated food is not sold in large amounts for the next 2 years how will consumers be educated? Furthermore, the logo itself is misleading. It looks like a flower in the center of the logo's circle, implying that irradiated food is natural. Food mutilated with gamma rays from radioactive waste is not my idea of a natural process. A more appropriate logo might have a mushroom in the center of the circle.

Finally - for whoever has read through, this far, my braying criticism of this regulation - I have one final comment. This concerns the requirement for labeling bulk produce - which I support. "The required information may be displayed to the purchaser with either: (1) The labeling of the bulk container plainly in view or (2) a counter sign, card, or other appropriate device bearing the logo and the term "treated with radiation"...This approach is consistent with the exemption provided in 21 CFR 101.22(e) for bulk fruits and vegetables that may have applied waxes or coatings. [51 FR 13391]." And here is the problem. Where I have lived in central New Jersey for over 15 years I have NEVER SEEN ANY RETAIL STORE, THAT SELLS BULK FRUITS AND VEGETABLES, THAT HAS COMPLIED WITH THE REQUIREMENT to label oiled or waxed cucumbers, apples, winter squash, etc. Laws are not worth the paper they are printed on if they are always violated and never enforced. Why should this newer labeling requirement for irradiated bulk produce be any better?

References

[1] Brunetti, A. P., et. al., "Recommendations for Evaluating the Safety of Irradiated Foods," Final Report Prepared for the Director, Bureau of Foods, FDA, July 1980.

[2] N. Raica, Jr., J. Scott and W. Nielsen, "The Nutritional Quality of Irradiated Foods," Radiation Res. Rev., 3 (1972), pp. 447-457.

[3] Elias, P. S. and A. J. Cohen, Radiation Chemistry of Major Food Components," Elsevier Scientific Publishing Co., New York, 1977.

[4] Merritt, Charles, Jr., "Qualitative and Quantitative Aspects of Trace Volatile Components in Irradiated Foods and Food Substances," Radiation Res. Rev., 3 (1972), p. 353-368.

[5] Life Sciences Research Office, Federation of American Societies for Experimental Biology. Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef. NTIS, AD-A045716, 1977.

[6] W. W. Nawar, "Reaction Mechanisms in the Radiolysis of Fats: A Review," J. Agric. Food Chem., 26, No. 1 (1978), pp. 21-25.

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RADIATION RESEARCH & PROCESSING FOR INDUSTRY SINCE 1968

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June 10, 1987

The Honorable Harold L. Colburn, Jr., Chairman, and Members
Assembly Health and Human Resources Committee
State House Annex CN-068
Trenton, New Jersey 08625

Dear Assemblyman Colburn and Committee Members:

I am responding to Assemblyman Kelly's Bill No. 3150, propos to ban the sale of irradiated food. I would like to emphasiz few important points in support of food irradiation which seem have been overlooked in the controversy. By taking scienti information out of context and misleading the public, th speaking out against the food irradiation process are doing Jersey consumers a great disservice.

First, I would like to briefly tell you about my involvement qualifications in the field. I have a Master's degree in F Science and Nutrition, and a B.S. in Home Economics with a ma in Nutrition. In addition to two years in food research Radiation Technology, Inc., including having reviewed most of published literature on irradiated foods, I have also worked a hospital Dietitian and Nutrition Counselor. I am a member of Institute of Food Technologists as well as the American Dietet Association.

The first important point about food irradiation is that it c not make a food radioactive. The types of sources and ene levels permitted for use with food by the U.S. Food and D Administration (FDA) were written into the Code of Fede Regulations because they are not capable of induc radioactivity in the treated food.

Second, it is misleading to imply or believe that irradiat treatment is for all foods, at all times, for all people. method of food processing or preservation is. Rather, a foo

treated for specific technical purposes, often where no alternatives exist. One such application is insect disinfestation of fruits and vegetables, particularly those imported from tropical areas. Ethylene dibromide (EDB), a chemical fumigant traditionally used to satisfy USDA quarantine requirements for some imported fruit, has been banned, and many others are being investigated and will surely be banned too, because they leave potentially dangerous residues on the treated food. Chemical additives in our food supply are becoming increasingly unpopular with the public. In many cases, irradiation offers the only effective alternative. Its use as a quarantine treatment is very promising.

Another timely need for irradiation of food is with poultry. The USDA and Radiation Technology, Inc. have each petitioned the FDA for approval of low dose irradiation to control the Salmonella problem in the poultry industry. The issue has been well publicized on T.V. and in the newspapers. USDA wants poultry with sufficiently low levels of pathogens as to not cause public health problems. According to USDA economists, low dose irradiation of contaminated chicken carcasses alone reduces Salmonella by 93% and could save $480.-805. million in public health benefits annually. These applications, pulled by industry need, and supported by government agencies involved with public health, should be available to consumers in New Jersey.

Food irradiation is being supported by the World Health Organization, the Food and Agriculture Organization, the U.S. Food and Drug Administration, the USDA Food Safety and Inspection Service, the American Council on Science and Health and the Council for Agricultural Science and Technology (CAST). CAST task force members include primarily researchers and scientists from universities and Federal government agencies. In addition, in 1980, after extensive review of decades of research on irradiated foods worldwide, a Joint Expert Committee on Food Irradiation of the FAO/WHO group concluded that "irradiation of any food commodity to an overall average dose of 1.0 Mrad presents no toxicological hazard." The Codex Alimentarius Commission, which develops international food standards, later adopted the Expert Committee's recommendation.

My last point deals with the amount of reasearch and testing that has been done on irradiated foods. I have read misleading statements to the effect that FDA approvals were not based on scientific research, but rather just on theory. The toxicological, chemical, nutritional and microbiological aspects of irradiated foods have been studied extensively. Based on information published in the Federal Register of April 18, 1986, FDA has reviewed over 400 studies alone on the toxicological safety of irradiated foods. I also know from experience that when submitting a petition to FDA for approval to irradiate a food, voluminous amounts of original research is required as supporting data. If there is insufficient data to support the safety or efficacy of the process, the petition will not be considered.

In conclusion, food irradiation is a technology for which the
is a growing need, and can provide the people of New Jersey wi
a solution for the problem of hazardous chemicals and bacteri
pathogens in our food supply. Let's offer them an alternati
for a safer, cleaner, more acceptable and varied supply of food
and not prevent irradiated foods from ever being offered on t
market in our state. Industry and consumers in New Jersey shou
have a right to the facts on food irradiation, and a right
make an educated choice.

Sincerely,

Lois Scheiner

Lois Scheiner
Director, Food Research

June 9, 1987

David Price
Committee Aide
Assembly for Health and Human
Resources
Room 455
State House Annex
Trenton, New Jersey CN068-08625

Dear Committee Aide Price:

I am incensed that the food I am and will be eating may be irradiated. Studies have shown that irradiation causes mutation to the molecular structure of food cells. Thus, our bodies may consider such "foods" as foreign substances (and not real food), with all the assimilation problems associated with same. The safety of eating such "foods" is more than questionable. What is the effect of eating mutated substances that our bodies no longer recognize as food? Depressed immune system? Cancer? We do not know!

Irradiation discourages worms, bugs and bacteria from eating foods. Here, these "lesser" creatures have more intelligence than humans, as they know enough (instinctively) to stay away from substances which no longer represent real food.

Perhaps nuclear proponents can find a better way to justify nuclear waste that using it to damage food quality and jeopardize the safety and lives of the human population.

I am imploring you to please support any bills to stop food irradiation.

Sincerely,

Loren Leith
P.O. Box 54
Essex Fells, New Jersey 07021

179X

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administ
Rockville MD 20857

JUN 15 1987

Harold L. Colburn, Jr., M.D.
Chairman
Assembly Health and Human Resources
c/o Mr. David Price
Office of Legislative Services
Room 455, CN-068
State House Annex
Trenton, New Jersey 08625

Dear Dr. Colburn:

This is in response to your letter of June 1, 1987, to the Commissioner of Food and Drugs, concerning the process whereby the Food and Drug Administration (FDA) arrived at its decision that irradiation of food under certain conditions is safe. In particular, you asked us to address allegations that FDA approval was based on theoretical considerations and not on experimental studies. You also asked us to address the claim that out of 400 studies on food irradiation, only five provided the basis for the approvals. I appreciate this opportunity to clarify for you the actual review and analysis procedures used by FDA in reaching decisions on this important issue.

In 1979 FDA established the Bureau of Foods Irradiated Food Committee (BFIFC) to develop criteria for assessing the safety of irradiated food. BFIFC reviewed a great deal of experimental data on the effect that radiation has on food. Half the members of BFIFC were experts in evaluating the results of toxicological testing, that is testing in which a substance is fed to animals to determine whether the substance causes any toxic effects. Based on their experience in reviewing such testing, the members of BFIFC sought to devise a design for testing irradiated food that would provide useful information on whether irradiated food is safe. The members of BFIFC concluded, based on the evidence that they reviewed, that the types of animal feeding tests that were most appropriate for evaluating the safety of irradiated food were not capable of detecting toxic effects from foods that had been irradiated at a low dose or from foods such as spices, which are only minor components of the food supply. The change in food caused by low-dose irradiation is simply too minor to be toxicologically significant. BFIFC concluded that the safety of certain uses of irradiation could be evaluated without data from animal feeding studies. This conclusion was based on the review of experimental data summarized in the bureau report entitled "Recommendations for Evaluating the Safety of Irradiated Foods." They did recommend, however, that the agency not approve the irradiation, at significant levels, of major food commodities without toxicity testing. I am enclosing a copy of this report.

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The second issue that you raised is related to the work of a second FDA committee, which was established to review the many animal feeding studies that have been conducted. This group, the Irradiated Foods Task Group (Task Group), had two major objectives. FDA had been asked to permit the irradiation of any food up to the dose approved in some international markets of 1 Mrad (10 kGy), an amount 10 times higher than the 0.1 Mrad approved by FDA for the irradiation of fruits. BFIFC had recommended that animal feeding tests be required before the agency approved irradiation at such levels. The Task Group was to determine whether the available animal feeding tests were adequate to provide a basis upon which the agency could approve irradiation at such doses. The Task Group's review was also intended to serve as a cross-check on the BFIFC recommendations. The Task Group was to look for any patterns or trends of adverse effects in animals fed irradiated food. If any adverse effects were found in animals fed irradiated foods under conditions that were predicted not to have such effects, the credibility of the BFIFC recommendations would have been seriously undermined. Adverse effects from foods irradiated at higher doses could also have raised serious questions.

The Task Group reviewed approximately 400 studies and found no patterns of evidence that would indicate that irradiation of food produced adverse toxic effects. Although much valuable information was gained from this review, most of the studies were subject to some scientific question. Only five long-term studies met all of the criteria for acceptability established by the members of the Task Group before they began their review. Each of these five studies supported the safety of irradiated food. Nevertheless, because only a handful of the available studies met all the standards adopted by the Task Group, the Task Group recommended against approving the use of irradiation on all foods at a dose up to 1 Mrad without additional data. FDA has not approved such use. I am enclosing copies of several documents describing the work of the Task Group.

Finally, to provide a more complete overview of the entire process, I am enclosing a paper by two of our scientists published in Food Reviews International in 1986 entitled "Irradiation of Foods - An FDA Perspective," by Pauli and Takeguchi. Pages 94-97 of the paper provide a more detailed summary of the series of reviews and decisions resulting in the current agency position on this subject. Also enclosed are copies of our Advance Notice of Proposed Rulemaking, Notice of Proposed Rulemaking, Final Rule, and Denial of Stay, which collectively describe the formal rulemaking over the last six years that bring us to where we are today.

I hope that you find this information to be helpful to you and your committee. If I can offer additional clarification, please let me know.

Sincerely,

John M. Taylor
Associate Commissioner
for Regulatory Affairs

Enclosures

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STATE OF NEW JERSEY
DEPARTMENT OF AGRICULTURE
ARTHUR R. BROWN, JR., SECRETARY
CN 330
TRENTON 08625

June 18, 1987

Honorable Harold L. Colburn, Jr.
223 High Street
Mount Holly, NJ 08060

Dear Assemblyman Colburn:

Re: Senate Bill 2571 and Assembly Bil 3150

The Department has reviewed the legislation pending in your committee sponsored by Senator Dorsey and Assemblymen Kelly and Loveys. These bills seek to prohibit the sale or distribution foods treated with radiation. Although the State Board of Agriculture has not taken a position on these bills, I would like t provide a few general comments.

I am not aware of any locally grown fresh fruits, vegetables or meats that are irradiated prior to being sold to the consumer. Although some of these commodities may legaly be treated by irradiation to extend the shelf life or to destroy undesirable organisms, in actuality, this treatment is not used. In addition, the Federal Food and Drug Administration requires tha fresh products treated with radiation must be labeled. Therefore, the consumer can make the choice whether or not to purcha these products.

The Federal Food and Drug Administration has reviewed this technology and has determined that at appropriate levels, it can be used without undue risk to consumers. The application of new technology, however, often leads to questions and the discussio of its merit. Since this technique is not used on locally grow produce, the expertise for reviewing the possible risks of food irradiation rests at the federal level and with the local unive sities.

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I am confident that the Committee will weigh that scientific knowledge before prohibiting its potential use in New Jersey.

I appreciate your consideration of these comments.

Sincerely,

Arthur R. Brown, Jr.

cc: Members of the Assembly Health Committee ✓
John H. Dorsey
John V. Kelly
Ralph A. Loveys

CAST®

COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

137 Lynn Avenue, Ames, Iowa 50010-7120 • (515) 292-2125

June 11, 1987

Mr. David Price
Office of Legislative Services
CN-068, Room 457
Statehouse Annex
Trenton, New Jersey 08625

Dear Mr. Price:

Thank you for your cordial reception of my telephone call this afternoon. I am sending herewith the 7 copies of the report on the wholesomeness of food treated with ionizing energy. It reviews the scientific world literature in words designed for nonscientists, and I believe you will find it a valuable source of information on the subject. The report was prepared by a multidisciplinary group of scientists with expertise in the subject. A number of the scientists had spent the major part of their careers in research on the process.

If feasible, I hope you will be able to introduce a copy of the report into the hearing record. Thank you for your cooperation.

Sincerely,

Charles A. Black

Charles A. Black
Executive Chairman of the Board

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Comments made by Dr. Myron Solberg during public hearing of the Assembly Health and Human Resources Committee on June 15, 1987.

I will first present credentials and make disclaimers. I am not a toxicologist, I am a professor of Food Science and the Director of the Center for Advanced Food Technology at Cook College, Rutgers University.

I began research in food irradiation in 1954 after returning from Korean War service. This was at MIT, which at that time was the center for food irradiation research. My Ph.D. thesis was entitled: "Growth Support Potential of Irradiated Foods for Microorganisms of Public Health Significance." It is mainly to the public health issues that I wish to speak today.

Before starting off, let me say that in 1964 I gave up my search for wealth, left industry, took a 20% pay cut, and came to the University. I have never regretted it. I do not work for and am not supported by any of the food irradiation companies.

Let me start by telling you what irradiation is. It is a tool for our use with which we can improve our quality of life. The irradiation source is an energy source and like any energy source, it must be treated with respect. The sun is an energy source. Misused it can cause cancer. Treated with respect it provides warmth and is the source of growth for plants which make up much of our food supply. Fire is another energy source. Treated without respect by Mrs. O'Leary's cow, a whole city burned. Handled properly it is life sustaining. Electricity is another energy source. We respect it. We have high power lines overhead, we have high voltage entering our homes. Surely it can harm us but respectful handling lets us live with the wonders of electricity. Thus we see that a radiation source is an energy source and like all energy sources, has risks. Control and respect minimize the risk. The benefits of radiation are many. In fact, while we fear radiation because of its cancer causing potential, we utilize radiation to cure cancers because it preferentially destroys rapidly growing cells preferentially.

But let's turn our attention to food irradiation. What does the irradiation of food do?

It destroys microorganisms - molds, yeasts, bacteria.

It inactivates growing cells. This is the same response mentioned in cancer treatment, the preferential inactivation of rapidly growing cells, which permits the prevention of sprouting in potatoes and onions.

It inactivates insects.

It inactivates parasites.

It breaks down complex materials making some more digestible and more available as nutrients.

What does irradiation of food not do?

It does not produce any unknown chemicals which are not present in foods which are unirradiated. These are the URPs which you may have heard about. URPs are figments of statisticians' imaginations. If a mass of molecules are irradiated, a certain number will be changed into new substances. The probability that some of these will be unique does exist but none have ever been discovered. In fact, the finding of a unique radiolytic product has been a desire of scientists since the earliest days of food irradiation. Such a substance would serve as a "marker" and allow us to determine the irradiation exposure or dose to which a food has been exposed. No such substance has been found and research is actively being carried out to-day, in search of a unique radiolytic product.

It does not destroy the nutritive value of proteins, carbohydrates, fats, minerals and many vitamins. It is important to realize that all foods will not be irradiated. There will be vitamins supplied by the variety of foods consumed. In addition we now do and will continue to supplement the food supply with vitamins when such needs are recognized and called for.

The bottom line in all of this is: "what can irradiation of food do for us? It can improve our quality of life. It will improve public health and microbial safety of food. It will reduce food wastes and therefore food costs. It will provide higher quality products in appearance, flavor and color. These are critical for nutrition, because it should always be kept in mind that food which is rejected by the consumer due to appearance, color, odor and for other reasons, provides no nutrition. Only food that is eaten provides nutritional value.

It should be clear that all foods will not be irradiated. Irradiation is not a panacea. That was our naive belief when I was a graduate student, but we quickly learned that only certain items lend themselves to the irradiation process. Of those, only the ones which do the job better than any other process available and those that provide economic feasibility will be used.

The best example of this is the one recognized in the legislation being proposed. The exemption of spices from the ban is written into the regulation. Irradiation is the

only way to change spices from an inoculum which hastens food deterioration and provides the basis of potential public health problems due to microbial disease.

This microbial disease is the real area of my interest and expertise. Let me state the problem by reading some remarks made by Commissioner Frank E. Young of the US Food and Drug Administration. These were recently published in "environment news digest."

"Two FDS scientists estimate that roughly one-third of all diarrheal episodes in the United States - somewhere between 24 million and 81 million cases annually - are of foodborne origin. The costs of these episodes, in terms of patient illnesses, medical expenses and lost wages are staggering; they produce substantial sickness and amount to billions of dollars each year. Diarrheal disease, often viewed as a short term nuisance for most of us, can bring death to certain vulnerable groups - to the very young, the very old, and those with comprised food immune systems. Recently, we have seen food-borne pathogens bring severe and often fatal complications in high risk populations such as pregnant women and fetuses infected with Listeria monocytogenes.

Today we know or suspect that some pathogens associated with food may cause or trigger certain chronic rheumatoid disorders, such as arthritis, Reiter's syndrome, and ankylosing spondylitis. And by influencing nutritional status and immune functions, foodborne pathogens may play a role in other disorders, such as respiratory infections.

In effect, the toll in human suffering from foodborne illnesses may be far greater than any of us might initially suspect.

Some pathogens, such as Listeria and Yersinia are of special concern because they seem to have penetrated one line of modern defense against foodborne illness - food storage at low temperatures. We have seen these microbes grow at refrigeration temperatures in the laboratory.

Deeply troubling is the outbreak of foodborne illness which tragically occurred in the summer of 1985 in Los Angeles County. In that incident, Listeria monocytogens in Jalisco brand Mexican style cheese led to forty-seven fatalities - including infant deaths and stillbirths."

These are the microorganisms of concern. The ones that cause diarrheal disease, Salmonella is the best known. You have heard me mention some of the others. There is no way to eliminate Salmonella from the food supply. the Salmonella cycle, as it is known, has been approached from many directions throughout the world and no country has been

able to break it. Food irradiation is the intervention or the hurdle to Salmonella which will permit us to break the pattern of this important food borne illness.

Let me quote to you from some remarks made by Michael Stiles of the University of Alberta in Canada, whom I met for the first time when I was asked to appear before the Canadian Food and Drug Directorate last year to inform them of the botulism hazard in processed foods. As printed in the ASM news (Vol. 53, No 5, 1987, page 257) "according to Michael Stiles of University of Alberta in Edmonton. Perhaps the clearest trend is that more and more types of microbes are being recognized at least for their potential role as food-borne pathogens. As the family of Enterobacteriaceae has expanded - Stiles notes 22 genera and 69 species - the fraction suspected of causing food-borne diarrheal disease also has grown." It is these organisms that irradiation will destroy to provide us with a safe food supply.

The FDA regulation does not go far enough to give us these benefits. It is the next regulation, which will increase the allowable does by 3 to 10 times and which will provide us with this improved quality of life which can come from foods free of the pathogens I have talked about.

Perhaps you have seen the Salmonella expose' on "60 Minutes." This was critical of the inspection service, but it is clear that we cannot inspect food safety into a product. We cannot make food "Salmonella free" through inspection. It doesn't work. The desired result can only be achieved by intervention and irradiation is the only intervention technology available.

In conclusion I want to urge you to defeat the legislation so that the citizens of New Jersey may have a safe food supply. I urge you not to increase the cost of food to the citizens of New Jersey and not to place New Jersey in an adverse industrial competitiveness position relative to other states.

In response to questions from Assemblyman Harold L. Colburn, Jr.

Related to unique radiolytic products, there are breakdown products but none are unique to irradiation. They are formed as ions but they are relatively stable.

Related to turtles.

These were spreading Salmonellosis. The problem was solved by banning their distribution. (This is not a feasible solution for poultry and red meat).

Related to cooking effects.

Thorough cooking will destroy Salmonella. Loose cooked scrambled eggs are not heated adequately to destroy Salmonella. The problem is not only in cooking. It is also a cross contamination problems. No matter how much we try to educate the public, the acts of placing the raw material which may contain Salmonella on a surface or of handling by hands and then placing goods which will not be cooked prior to eating or of handling these foods without adequate hand washing, will be committed in the home, in the back room of the market and in the food service establishment or restaurant.

(The prevention is to eliminate the Salmonella from the raw product. The only means to do this, which is available today, is irradiation).

MORRIS COUNTY MEDICAL SOCIETY

executive office: 51 ELM STREET MORRISTOWN, N.J. 07960 • telephone: (201) 5

June 10, 1987

Hon. Rodney P. Frelinghuysen
10 Park Place
Morristown, NJ 07960

Dear Rod:

The Executive Committee of the Morris County Medical Society has reviewed the pertinent legislation regarding irradiation of foods. This includes **A-3150, A-2603** and **S-1801.**

With regard to **A-3150**, the Society is of the opinion that there is not enough scientific information available to determine whether or not irradiation adds any harmful substance to the preserved food and that until such information can be obtained legislation against it should not be enacted.

Regarding **A-2603** and **S-1801**, this Society concurs with the opinion expressed by The Medical Society of NJ that there is no known evidence of public harm from irradiated foods and menu warnings would only alarm the public needlessly.

Thank you for the opportunity to comment on these bills. If you have any questions, please feel free to contact us.

Yours sincerely,

Anne

Mrs. Anne A. Marek
Executive Director

248X

Lorraine Gold and
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TELEPHONE (201) 362-9321

new mailing address: 21 Hardwick Road

June 30, 1987

David Price,
Office of Legislative Services
State House Annex
CN 068
Trenton, NJ
08625

Re: A3150 - Kelly's Food Irradiation Bill

Dear Mr. Price:

We attendedthe Food Irradiation Hearing in Trenton and would like to offer our thoughts about the testimony of the man from Isomedix, Inc. His contention that consumers are going to be looking for food that is labeled "irradiated" as their free and rightful choice is the pure wishful thinking of a person whose livelihood is tied up with this technology.

We would suggest to the committee that they consider the reactions of citizens around this state when asked to store, even temporarily, radium contaminated soil in their communities. This soil contains low level radioactivity, at most, and yet the idea of this is enough to spur the average citizen to take to the streets. Let's put two and two together and realize that there is no hope of consumer acceptance of clearly labeled irradiated food.

This leaves us to suppose that once the millions of dollars are spent to develop food irradiating plants (at great risk to "host" communities) the food will NOT be clearly labeled. Where will this leave the consumer's rights and free choice?

We would like to commend the Chair, Assemblyman Coburn, for the admirable way he conducted the hearing. We appreciate the time and concern he is devoting to this issue.

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Please find enclosed a recent Star ledger article about Salmonella. This is sent to illustrate one more example of why there is no need for the radical and destructive process of food irradiation.

Very truly yours,

William J. Gold, Esq.

Lorraine Gold

Enc.

cc Assemblyman Hayatian
Assemblyman Littell
Assemblyman Kelly
Speaker Hardwick
Assemblyman Coburn

250X

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July 3, 1987

BY COURIER

Mr. David Price
Committee Aide
Assembly Health & Human Resources Committee
State House Annex
Trenton, NJ
USA 08625

Dear Mr. Price:

Re: Food Irradiation Testimony/Information Submission Relevant to 15 June 1987 Public Hearing

Attached are nine copies of the testimony that our Mr. Dick McKinnon intended to present at the public hearing. However, we were advised by Dr. George Giddings of Isomedix Inc. that, we would not be permitted to testify due to the large number of "local" interests wishing to do so.

In lieu, we submit the attached for your use/the committees review.

Should the committee require additional information or expert testimony on the safety of irradiation facilities or the shipment of Cobalt 60, we would be pleased to provide it.

Yours truly,

B.K. Wilson

Bruce K. Wilson
Director of Marketing
AECL-RCC
Industrial Irradiation Division

cc: F.M. Fraser
D. McKinnon

Attachments

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Statement prepared for delivery to: June 10, 1987

THE NEW JERSEY STATE LEGISLATURE
HEALTH AND HUMAN RESOURCES COMMITTEE
PUBLIC HEARING JUNE 15, 1987

on

ASSEMBLY BILL No. 3150 and SENATE BILL No. 2571
which would prohibit the distribution and sale of irradiated food

Statement by: Mr. Dick McKinnon
General Manager of Engineering
Atomic Energy of Canada Ltd.
Radiochemical Company
Industrial Irradiation Division
P.O. Box 13500
Kanata, Ontario,
Canada
K2K 1X8
phone: (613) 592-2790

Statement Content/Nature:

- in support of Food Irradiation
- against the bills
- the safety of irradiation facilities
- the safety of Cobalt-60 transport and use
- the disposition of Cobalt-60
- the right of the consumer to have a choice

Statement Text (Presentation time approximately 15 minutes)

Introductory words of thanks to the chairperson and committee for being given the opportunity to testify.

ATOMIC ENERGY OF CANADA LIMITED (AECL) is the world's leading supplier of industrial gamma irradiators and Cobalt-60 sources. Approximately 25 of the 40 commercial gamma irradiators in the United States today were designed and manufactured by AECL. Almost all of the 40 irradiators use Cobalt-60, produced by AECL, as the source of gamma radiation. AECL has produced research and industrial irradiation systems and industrial cobalt sources since the early 1950's. In addition, AECL has been involved in food irradiation research and development activities in conjunction with Canadian and international authorities from academia, industry and government.

.../2

AECL's position regarding food irradiation is; in support of the commercial use of the process, is in support of the qualified scientific and public health authorities that have approved the process, and is in support of the consumer's right to choose irradiated food.

Others will or have already testified on the safety of irradiated food. I will confine my testimony to three subject areas:

1) the safety of industrial gamma irradiation facilities

2) the safety of the transportation of Cobalt-60

3) the disposition of "used" Cobalt-60

We believe these subjects are relevant to the bills under discussion, and are aware that opponents of food irradiation have raised these issues in their arguments.

Our position regarding these three subjects is:

1) Well designed and properly operated industrial gamma irradiation facilities which use Cobalt-60 present no greater and most likely less risk to workers, the public and the environment than other processing technologies.

2) There has not been, to the best of our knowledge, any incident involving the shipment of industrial Cobalt-60 sources which resulted in any radiation exposure to the public, or presented any significant risk of exposure.

3) AECL supplied Cobalt-60 that is no longer wanted by industrial users will be recovered by AECL for reuse, reactivation or disposal in Canada.

4) Cobalt-60 is not a waste product of nuclear power generation or nuclear weapons programs. It is a deliberately produced isotope of Cobalt-59 that is only produced when the market requires it. AECL alone has the production capacity to meet anticipated worldwide demand for Cobalt-60, and has the potential to increase Cobalt-60 production capacity to respond to unanticipated demand.

.../3

5) In the United States and Canada there are effective governmental regulations, control agencies and penalties for non-compliance which protect the public, workers and the environment.

6) The potential for abuse or misuse of any type of machinery or industrial process always exists. The risks associated with potential abuse or misuse of industrial Cobalt-60 sourced gamma processing systems are no greater than any other currently accepted food processing technology.

Now, I would like to present an abbreviated version of a technical paper that is included in our written submission to the committee. This paper addresses the safe design and operation of Cobalt-60 industrial irradiation facilities and the handling of Cobalt-60 sources.

(Refer to the attached technical paper)

Concluding Remarks

The opponents of food irradiation have and no doubt will continue to repetitiously raise questions regarding facility and source safety. We, the manufacturers, the regulatory and control agencies, and the facility owners are confident that, when given the opportunity for an impartial hearing before technically qualified authorities, we can satisfactorily address any concerns or arguments. The difficulty however lies in communicating technical data to non-technical authorities. I have tried to the best of my ability to do this in the past 15 minutes, and have enclosed in the testimony packages more detailed information.

If time permits, I will be happy to answer any questions that you may have. Thank you.