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Food and Drug Administration

21 CFR Part 179

Irradiation in the Production, Processing, and Handling of Food; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 81N-0004]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to permit additional uses of ionizing radiation for the treatment of food. These regulations: (1) Permit manufacturers to use irradiation at doses not to exceed 1 kiloGray (kGy) to inhibit the growth and maturation of fresh foods and to disinfect food of arthropod pests, (2) permit manufacturers to use irradiation at doses not to exceed 30 kGy to disinfect dry or dehydrated aromatic vegetable substances (such as spices and herbs) of microorganisms, (3) require that foods that are irradiated be labeled to show this fact both at the wholesale and at the retail level, and (4) require that manufacturers maintain process records of irradiation for a specified period and make such records available for FDA inspection. These regulations are promulgated on the agency's initiative and are necessary to permit the safe use of ionizing radiation. This document responds to comments on the February 14, 1984, proposed rule (49 FR 5714).

DATES: Effective April 18, 1986; objections by May 19, 1986.

ADDRESS: Written objections and request for a hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Clyde A. Takeguchi, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Under section 409 (b) and (d) of the Federal Food, Drug, and Cosmetic Act (the act), the Secretary may approve a food additive petition from an interested person or may propose the issuance of a food additive regulation upon the Secretary's own initiative (21 U.S.C. 348 (b) and (d)). It is less common for FDA, acting as the Secretary's delegate, to propose and then establish a regulation itself, than to respond to a sponsor's petition. In the case of food irradiation, FDA had, before 1981, approved several food additive petitions for the use of various sources of radiation on certain foods and food-packaging materials (21 CFR Part 179). Subsequent to these approvals, an FDA committee evaluated testing criteria that would be necessary to support the safety of food irradiation for various uses.

In the Federal Register of March 27, 1981 (46 FR 18992), FDA published an advance notice of proposed rulemaking that announced the availability of the Bureau of Foods' (now the Center for Food Safety and Applied Nutrition) Irradiated Food Committee (BFIFC) Report (Ref. 1), which outlined a course of action for assuring the safety of irradiated foods, and requested comments on the overall approach.

In the Federal Register of February 14, 1984 (49 FR 5714), FDA published a proposed rule that would: (1) Establish general provisions for food irradiation, (2) permit the use of food irradiation at doses not exceeding 1 kiloGray (kGy) (100 kilorads: 100 krad) [1] for inhibiting the growth and maturation of fruits and vegetables and for insect disinfestation of food, (3) allow irradiation to be used for microbial disinfection of certain dried spices and dried vegetable seasonings at a dose not to exceed 30 kGy (3 Mrad), (4) eliminate the current irradiated food labeling requirements for retail labeling, and (5) replace the current sections (21 CFR 179.22 and 179.24) dealing with the irradiation of food with new §§ 179.25 and 179.26 (21 CFR 179.25 and 179.26). The proposal responded to comments on the advance notice of proposed rulemaking.

Apart from that ongoing rulemaking, FDA has approved a number of food additive petitions to provide for the safe use of gamma radiation at doses up to 10 kGy (1 Mrad) to control insect infestation and microbial contamination in dried herbs, spices, and vegetable seasonings (48 FR 30613, July 5, 1983; 48 FR 46022, October 11, 1983; 49 FR 24966, June 19, 1984; 50 FR 15415, April 18, 1985) and in dry enzyme preparations (50 FR 24190, June 10, 1985). FDA also issued a final rule on July 22, 1985 (50 FR 29658) which amended 21 CFR 179.22(b) in response to a petition to provide for the safe use of gamma radiation at doses up to 1 kGy (100 krad) to control *Trichinella spiralis* in pork.

The act requires that a food additive, including a source of radiation used to process food, be shown to be safe under the proposed conditions of use before use of the food additive can be approved. That is, the agency must be assured with reasonable certainty that no harm will result from irradiation of food. A source of radiation is specifically defined as a food additive in section 201(s) of the act (21 U.S.C. 321(s)). The Senate report on the Food Additives Amendment of 1958 made clear that "[s]ources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term 'food additive' as defined in this legislation." S. Rept. 2422, 85th Cong., 2d Sess. 63 (1958).

Section 409 of the act lists the criteria which must be considered by the agency before a food additive regulation is issued. The statute does not prescribe what safety tests should be performed but leaves that determination to the discretion of scientists. The definition of safety, as drawn from the legislative history of the Food Additives Amendment of 1958, has been codified in 21 CFR 170.3(i) as follows:

(i) "Safe" or "safety" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended condition of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any

[1] The Systeme Internationale (SI) unit for expressing the amount of absorbed radiation dose is the Gray (joules/kilogram, abbreviated GY). An older unit commonly used is the rad. The equivalent value in rads (100 rad = 1 Gy) will be enclosed in parentheses when referring to the amount of absorbed radiation. The prefixes kilo (k) and mega (M) represent a thousandfold and a millionfold, respectively. Thus, kilorad means a thousand rads and a megarad means a million rads.

chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

In passing the Food Additives Amendment of 1958, Congress recognized that it is impossible to establish with complete certainty the absolute harmlessness of any chemical substance. The concept of safety used in the amendment involves reducing uncertainty about the safety of an additive to the point where the agency can reasonably conclude that no harm will result from its proposed use.

This objective can be achieved in a variety of ways. To determine whether consumption of a substance is safe, the agency considers the amount and identity of the substance ingested in light of what is already known regarding its toxicity. Ordinarily, animal feeding tests are essential for assessing toxicity of a substance. Not all situations require the same amount or type of testing, however, to determine whether use of an additive is safe. The degree of effort expended in reducing uncertainty about the safety of an additive must relate in some way to the likelihood that use of the additive poses a potential health risk to the public. Testing that is unlikely to provide information that would reduce uncertainty regarding safety should not be required. To do otherwise would waste scarce scientific resources that could be used for more productive purposes.

II. Comments

The agency received over 5,000 comments on the proposal. Many of the comments simply stated opinions for or against permitting food irradiation or requiring special labeling but identified no substantive issues to which the agency can respond. For example, some comments expressed concern that food might become radioactive, but none provided factual support. Other comments acknowledged that irradiation of food will not make the food radioactive. The agency believes that the proposal adequately addressed the issue of induced radioactivity in food (see 49 FR at 5716). Because no evidence has been submitted to contradict FDA's finding that the irradiation of food does not cause the food to become radioactive, no further discussion of this issue is necessary.

Many of the comments were concerned about the formation and the safety of radiolytic products, and the effect of irradiation on nutrients in food. A majority of those comments stated that more studies were needed because the long-term effects of these radiolytic products have not been ascertained with enough certainty to justify the conclusion that the use of irradiation is safe. The substantive comments and FDA's response to each are discussed below.

A. Safety

Before responding to the substantive comments relating to safety, the agency believes it would be useful to explain again its safety assessment of food irradiation and its conclusions concerning the safety of foods irradiated in compliance with this regulation. A summary of FDA's position on safety is set forth below.

In the proposed rule, the agency stated "* * * that the safety of food irradiation below 1 kGy (100 krad) has been established * * * because: (1) Irradiation will not make the food radioactive, and thus cannot expose the consumer to radiation; (2) the chemical differences between irradiated foods processed at these doses and nonirradiated foods are too small to affect the safety of the foods; (3) food irradiated at doses up to 1 kGy (100 krad) will have the same nutritional value as similar foods that have not been irradiated; and (4) the balance between microbial spoilage organisms and pathogenic organisms is not adversely affected by radiation doses below 1 kGy (100 krad)" (49 FR 5716).

The agency has followed the same general procedures in the development of regulations for the use of sources of radiation as are followed in the development of regulations for other food additives. Under the act, the agency's primary responsibility is to determine that the additive is safe under the proposed conditions of use. Since the 1960's when the first petition for the treatment of food with radiation sources was submitted, the agency has been confronted with the question of what test procedures are appropriate to establish reasonable certainty of no harm for use of radiation sources in the treatment of food. In the absence of adequate data on the chemical changes in food treated with radiation and information on the nutritional quality of such food, FDA concluded that petitioners should submit animal feeding studies to demonstrate the "wholesomeness" of irradiated food. In those instances where petitioners have provided adequate chemical and nutritional data to the agency, FDA has not required petitioners to submit long-term animal feeding studies. For example, FDA has issued regulations authorizing the use of x-rays for inspection of food, microwaves for heating food, and ultraviolet radiation for treating food based on chemical analyses (see 21 CFR 179.21, 179.30, and 179.39, respectively).

In 1979, FDA established its Bureau of Foods Irradiated Food Committee (BFIFC) to review the existing agency policy concerning the irradiation of foods. BFIFC's main task was to make recommendations regarding the establishment of those toxicologic testing requirements appropriate for assessing the safety of irradiated foods. BFIFC's recommendation focused on making the degree of testing compatible with the potential risk as indicated by the level of anticipated human exposure. BFIFC recognized that safety assessments of irradiated food should be based on: (1) Projected levels of human exposure to the food; (2) estimates of the identity, amount, and potential toxicity of new chemical constituents generated in the food by the irradiation process; and (3) state-of-the-art sensitive toxicological tests. BFIFC completed its review and submitted its final report in July 1980 (Ref. 1).

BFIFC recognized that no single approach provided sufficient data to estimate the percentage of food consumption that might consist of irradiated food. Hence, in projecting human exposure to irradiated food, BFIFC used estimates of total food consumption, dietary items proposed for irradiation, and the percent of each dietary item which may be irradiated. Using a rough estimate based on these factors, BFIFC suggested that as much as 40 percent of the total diet could be irradiated, but anticipated that actual human exposure would not exceed 10 percent of the diet.

Further, the committee considered those chemical constituents generated by irradiation, also known as radiolytic products. BFIFC assumed that some radiolytic products may be unique to irradiated foods, and created the term "unique radiolytic products" (URP's) to mean substances not known to be present in nonirradiated food. However, BFIFC recognized that scientists do not know the extent to which these substances, although characterized as URP's, may actually be present as common constituents of the human diet.

BFIFC reviewed the available literature dealing with radiation chemistry, the identification and quantification of substances produced in foods as a result of irradiation, and found that the amount of radiolytic products generated is primarily dependent upon the amount of energy

absorbed by the food. Based on data showing how much chemical change is likely to be caused by a given amount of radiation energy, BFIFC concluded that irradiation of food at 1 kGy (100 krad) would generate approximately 30 parts per million (ppm) of radiolytic products. Experiments have shown that very few of these radiolytic products are unique to irradiated foods; approximately 90 percent of the radiolytic products identified by BFIFC are known to be natural components of food (Ref. 1). BFIFC found the remaining 10 percent of the radiolytic products to be chemically similar to known natural food components. Because of this chemical similarity, those radiolytic products are likely to be toxicologically similar also. Because natural components of food are not well characterized at the parts per million level, some radiolytic products assumed by BFIFC to be unique may actually be natural components of foods. However, even if 10 percent of the radiolytic products are unique, their cumulative concentration in food irradiated at 1 kGy (100 krad) would be only 3 per million, one-tenth the concentration of 30 parts per million for all radiolytic products. Moreover, the concentration of any single URP will probably be less than 1 part per million for food irradiated at 1 kGy (100 krad). Because different portions of a food being irradiated will receive different doses, the average radiation dose absorbed by the food will necessarily be less than the maximum permitted dose. Therefore, the concentration of URP's generated in food from irradiation should be even lower than the upper bound estimate calculated by BFIFC.

BFIFC concluded that because of the extremely low potential concentration of individual URP's in foods irradiated at doses below 1 kGy (100 krad), and because any URP's are likely to be toxicologically similar to other food components, it would be virtually impossible to detect potential toxicological properties of these substances. The current state-of-the-art toxicity tests are not sensitive enough to detect the potential toxicity of URP's at these low levels unless the URP's are far more potent than experience in the radiation chemistry of foods and in toxicology would suggest.

Because the potential concentration of URP's in irradiated food is low, BFIFC concluded that food irradiated at doses not exceeding 1 kGy (10 krad) is wholesome and safe for human consumption, even where the food that is irradiated may constitute a substantial portion of the diet. Consequently, the committee recommended that foods irradiated at doses below 1 kGy (100 krad) be considered safe for human consumption without the requirement of toxicological testing. BFIFC based this recommendation on radiation chemistry and on the anticipated low levels of human exposure to any URP's generated in irradiated foods.

The committee further concluded that a food (e.g., nutmeg) that comprises only a small fraction of the human diet (i.e., no more than 0.01 percent of the diet) and that is irradiated at doses up to 50 kGy (5 Mrad) would necessarily contribute far fewer radiolytic products to the daily diet—approximately 20 times less—than a food representing a significant fraction of the diet (e.g., 10 percent) irradiated at 1 kGy (100 krad). Consequently, BFIFC recommended that foods comprising no more than 0.01 percent of the daily diet and irradiated at 50 kGy (5 Mrad) or less also be considered safe for human consumption without toxicological testing. BFIFC based this recommendation on radiation chemistry and the anticipated low levels of human exposure to any URP's generated in irradiated foods.

The agency agreed with the scientific rationale and conclusion reached by BFIFC that an adequate margin of safety could be demonstrated for irradiated foods without the requirement of toxicological testing and advised its recommendations concerning the safety of foods irradiated at the proposed dosage levels (March 27, 1981; 46 FR 18992).

Subsequently, in 1981, FDA's Bureau of Foods established the Irradiated Foods Task Group to review all available toxicological data concerning foods treated by 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 response between studies, and to summarize the experimental results at the end of the review (Refs. 2 and 3).

The data review proceeded in three phases. In phase I, all relevant toxicology studies were identified from FDA files and from the open literature. In phase II, 441 of these studies were obtained in hard copy and summarized. These summaries categorized studies as: (1) "Accepted," if on initial examination the study appeared to be reasonably complete; (2) "accepted with reservation," if the testing, on initial summary review, appeared acceptable but had some serious deficiencies interfering with interpretation of the data; or (3) "rejected," if there were inadequacies of the experimental design or data collection, or if dietary problems existed in the study that would prevent a valid evaluation. In phase III, 99 studies that either raised questions concerning the possibility of adverse effects or that appeared to support a conclusion that the irradiated food studied is safe were examined in detail and reported (Ref. 4).

Based on its examination of all the data, the Task Group concluded that studies with irradiated foods do not show adverse toxicological effects. However, the Task Group further concluded that traditional toxicological testing of food irradiated at doses below 1 kGy (100 krad) cannot be expected to provide meaningful answers to toxicity questions regarding such irradiated foods. The Task Group based this conclusion on several major reasons: (1) Nutritional imbalances created in the test animal fed high levels of irradiated or nonirradiated foods would tend to mask any potential toxicological manifestations; (2) the low concentration of any potentially toxic radiolytic products in the irradiated foods would prevent significant exaggeration of the amount of radiolytic products in a test diet; and (3) such toxicological testing is currently too insensitive to measure toxicity because the concentrations of URP's potentially present in the irradiated foods tested are simply too low. Based on its review of all studies, including those which tested food irradiated at doses more than an order of magnitude higher than 1 kGy (100 krad), the Task Group agreed with BFIFC's conclusion that there was an adequate margin of safety for foods irradiated below 1 kGy (100 krad). Hence, the Task Group also agreed that toxicology tests on foods irradiated at 1 kGy (100 krad) or below are not needed to support a conclusion that such foods are safe.

Based on the findings, rationale, and conclusions of BFIFC and the Task Group, FDA concludes that food irradiated at doses not exceeding 1 kGy (100 krad) is safe for human consumption. The agency further concludes that use of this level of irradiation should be exempt from requirements for toxicological testing because such testing would not be able to measure any toxicological properties of radiolytic products present in irradiated foods. In addition, the agency concludes that irradiation of dry or dehydrated aromatic vegetable substances is safe for human consumption at higher doses. The agency has determined that irradiation at doses no higher than 30 kGy (3 Mrad)

will be adequate to accomplish the intended microbial disinfection of dry or dehydrated vegetable substances. The agency emphasizes that although toxicological data may sometimes be helpful in evaluating the safety of irradiated foods, such data are not scientifically necessary for determining the safety of radiation for the uses and doses encompassed by this regulation.

In addition to studies available in the published literature, the U.S. Department of Agriculture (USDA) has made available through the National Technical Information Service (49 FR 40823; October 17, 1984) final reports of certain contracted animal toxicological studies of radiation-sterilized chicken and reports on chemical changes in food caused by irradiation. The agency has reviewed studies involving mice and dogs fed radiation-sterilized chicken meat and concludes that these studies do not show any treatment-related effects (Refs. 5 and 6). These studies are discussed in further detail in the responses to those comments which reference the USDA studies.

1. Radiolytic Products

1. Many comments expressed the opinion that the radiolytic products produced during irradiation would made the food harmful. Some comments stated that the radiolytic products are free radicals and that ingestion of these free radicals would be harmful. Other comments stated that the free radicals may later form toxic substances.

The agency disagrees that free radicals or toxic substances will be produced in food at unsafe levels under the conditions prescribed by this rule. The issue is not whether free radicals, hypothetically, can later form toxic substances, but whether the formation of a toxic substance is sufficiently probable to raise questions about the safety of the irradiated food. Although the generation and subsequent reaction of free radicals comprise the major route by which radiolytic products are formed, such reactions are also common during conventional food processing and storage operations. As was discussed above, substances that are chemically similar to radiolytic products are often formed or are present in foods that are not irradiated.

The important issue the agency must consider with regard to radiolytic products is the probability that a toxic radiolytic end product may be formed and whether such a product would be present in sufficient amounts to make the food unsafe. The agency has no evidence to cause it to change its position that the chemical differences between foods irradiated at the doses allowed by this regulation and nonirradiated foods are too small to cause concern about the safety of the irradiated foods.

2. Some comments expressed the opinion that irradiated foods are unsafe because ingestion of irradiated foods may result directly in toxic free radical and peroxide formation within the body.

The agency disagrees. Although irradiation produces free radicals as reactive intermediates in the food itself, the high water content of all fresh food provides a medium for their rapid degradation after irradiation. Thus, they are not likely to persist or be present at all in food by the time that food reaches the consumer. However, irradiated dry spices and seasonings are examples of foods in which free radicals are known to persist for long periods of time. Nonetheless, the manner in which these foods are used—as ingredients in other foods that contain water—provides a means for rapid dissipation of the free radicals, thereby precluding their ingestion.

While peroxides are sometimes formed in irradiated foods, they are also formed in foods that are not irradiated. The agency has no evidence to suggest that irradiated foods would be metabolized differently from nonirradiated foods and thus form unique or toxic free radicals or peroxides within the body. Therefore, the agency believes that concerns about the safety of irradiated foods as expressed in these comments are unfounded.

3. One comment stated that "[a]ny preservation of foodstuffs by irradiation at any dose may be unwise," and that gaseous oxygen from air gives rise to free radicals, peroxides, and hydroperoxides. The comment also stated that increased concentration of hydrogen peroxide ordinarily results from irradiation. The comment noted that "[t]he addition of hydrogen peroxide to food as a preservative has been prohibited in a number of countries, notably Japan, as a contributor to carcinogenesis."

The formation of detectable quantities of hydrogen peroxide, organic peroxides, and hydroperoxides during irradiation of foods in the presence of oxygen is well documented, and food processors normally try to minimize contact of their products with air during processing and packaging. Peroxides result from free radical chemistry, as discussed earlier, between oxygen and the primary radiolytic products from the carbohydrates, fats and oils, and water present in food. The potential biological consequences of the thermal degradation of the intermediate peroxides and their reactions with the multitude of food components have been addressed by a number of researchers (Refs. 7, 8, and 9).

FDA considered the potential carcinogenicity of hydrogen peroxide in its final rule permitting the use of hydrogen peroxide as an indirect food additive for sterilizing polyethylene food contact surfaces used for food packaging (46 FR 2341; January 9, 1981). The agency had specifically addressed a Japanese report of a bioassay of hydrogen peroxide performed with C57B mice in which the authors had indicated that the chemical may have caused duodenal cancer. Upon review and after consultation with the authors of the study, the agency stated that the evidence was insufficient to conclude that hydrogen peroxide is a carcinogen (46 FR 2341; January 9, 1981).

In that document, the agency also considered the issue of human exposure to hydrogen peroxide in food and concluded that milk packaged in materials sterilized by hydrogen peroxide would contain hydrogen peroxide at a level no greater than 100 parts per billion at the time of packaging. Moreover, after 24 hours, the hydrogen peroxide concentration would fall to about 1 part per billion, i.e., more than 99.9 percent of the hydrogen peroxide will no longer be present in the food.

Similar considerations leads the agency to conclude that any hydrogen peroxide produced during irradiation of fruits and vegetables or meats in compliance with this final rule would be rapidly degraded to negligible levels by natural enzymes and natural antioxidants in the food. Furthermore, any residual hydrogen peroxide, if present, would be considerably less than that encountered ordinarily in foods and environmental sources.

Organic hydroperoxides, formed by reaction of radicals resulting from reaction of oxygen with primary radiolysis products, are both thermally and chemically unstable and decompose to various aldehydes, ketones, alcohols, and hydrocarbons which constitute the primary radiolytic end products also identified as components of both unprocessed and conventionally processed foods. The yields of these substances formed under the conditions of this regulation are sufficiently low as to raise no concerns regarding safety.

Finally, microbiological studies that have reported toxic effects of irradiated aqueous sugar solutions in which peroxides and peroxo radicals are generated are discussed in paragraphs 21 and 22 of this preamble. The agency

has concluded that these studies are inappropriate models for assessing the safety of irradiated foods.

4. Some comments stated that no radiolytic products are unique and noted that the U.S. Army Natick Laboratory found no unique products in irradiated meats. These comments indicated that the term "unique" is misleading and should not be used.

The BFIFC report used the term unique radiolytic products (URP's) to describe substances produced in food during irradiation which have not been shown to be present in nonirradiated food. The BFIFC report recognized, however, that substances characterized as URP's may be normal minor constituents in the human diet that have simply not been detected through routine analysis of nonirradiated food.

As stated in the proposal, the agency agrees that some radiolytic products assumed to be unique may well be natural or common components undetected in nonirradiated food. However, it is impossible to demonstrate with absolute certainty that that will always be the case for all radiolytic products. Therefore, the agency cannot be certain that all radiolytic products are normal components of the human diet. To be prudent, the agency has assumed, for purposes of safety assessment, that some minor radiolytic products present may not be normal components of the human diet, and, thus, may be unique to the process. Based upon such conservative assumptions, the agency concludes that the amount of potential URP's would be so low as not to pose a safety problem.

5. One comment asked, "what happens to pesticide residues on produce when they undergo irradiation treatment? What are the health risks to humans?"

A pesticide chemical, like any other chemical component of food, will possess a certain level of sensitivity to ionizing radiation. The degree of sensitivity of a pesticide chemical to the primary ionizing energy and to chemical reaction with primary radiolytic products from other constituents of a food matrix will depend on the molecular structure of the pesticide. As is the case with other chemical components of a food, the total yield of radiolytic products from irradiation of any given pesticide will be a function of the amount of pesticide present, as well as its sensitivity to radiation.

The BFIFC estimated that the sum of all radiolytic products produced by irradiation at 1 kGy (100 krad) would be no more than 30 parts per million in food. 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. Because such low levels of pesticide residues are expected in food, the agency believes that the total amount of radiolytic products from a pesticide chemical that may be consumed from foods irradiated in compliance with this regulation at doses below 1 kGy (100 krad) will be virtually nil. Therefore, the agency concludes that the potential toxicity of each radiolytic product from a pesticide chemical residue on foods that are irradiated would be negligible and that such pesticide residues do not pose a hazard to health.

2. Spices

6. One comment stated that foods such as spices comprise more than 0.01 percent of the daily diet and that the proposed rule was inconsistent with BFIFC's recommendation that irradiation of foods constituting less that 0.01 percent of the diet be considered safe up to 50 kGy (5 Mrad).

The agency agrees that spices, in total, may constitute more than 0.01 percent of the daily diet. The agency has estimated a probable intake of dried spices and culinary herbs of up to 3 grams per person per day. For the general population, this constitutes 0.1 percent of the total diet of 3 kilograms.

The comment was apparently confused by terminology in the BFIFC report recommending that a "food class" which contributes 0.01 percent or less to the daily diet be considered safe for irradiation at doses up to 50 kGy (5 Mrad). The 0.01 percent in the recommendation was intended to refer to the dietary contribution of an individual spice (e.g., nutmeg or turmeric) as a "food class," not all spices as a "food class." Because radiolytic products from different spices are likely to be different, there is no reason to add the amount of radiolytic products from one spice, such as nutmeg, to another spice, such as turmeric, when evaluating safety. The intent of BFIFC's recommendation was not to set a precise dietary percentage limit of 0.01 percent but rather to acknowledge that the amounts of radiolytic products that would potentially be consumed from irradiated dried spices and seasonings are so small that such irradiated foods can be considered safe as ordinarily used. Neither the proposal nor the final regulation permitting the irradiation of spices at 30 kGy (3 Mrad) is inconsistent with BFIFC's recommendation.

7. Some comments on the proposed rule expressed concern that large amounts of irradiated spices and seasonings used by certain ethnic groups in their food would exceed safe consumption levels. The comments provided no information on which to base such a concern.

The agency recognizes that dietary patterns differ between groups of people and that certain groups consume more spices and seasonings than do other groups. Nevertheless, the agency has no reason to believe that any ethnic group will consume any irradiated spice or seasoning in amounts that would raise any safety concern, even considering dietary variations among ethnic groups. A single spice or seasoning would still be a minor ingredient in the diet. Moreover, as discussed in the previous response, the radiolytic products from one spice are different from those of another spice; therefore, their effects, if any, will not be cumulative.

8. The agency invited comments on the list of spices that is considered appropriate for irradiation. Comments recommended including those substances listed in § 182.10 *Spices and other natural seasonings and flavorings* (21 CFR 182.10), as well as other spices, seeds, and herbs commonly used as minor flavoring ingredients, and including teas and other vegetable seasonings. Some comments also stated that a specific list of spices was unnecessary and a phrase such as "herbs, seeds, and spices" should replace the individual listing of spices. One comment stated that to prohibit treating a spice mix because one minor ingredient is not on the list is not logical and suggested an alternative approach of granting overall approval to seasoning and flavoring substances currently considered generally recognized as safe because their safety would not be significantly changed by irradiation.

The agency disagrees that natural flavors should necessarily be included in the list and is not permitting the use of irradiation for natural flavors at this time. Natural flavors are components of food ingredients that have undergone some processing. Such flavors may be in solid or liquid form. The agency's conclusion that minor ingredients such as dried spices and seasonings may be irradiated safely was based on the fact that the amount of chemical change in the solid, dry state of a food is less than would occur when substantial portions of liquid are present and that dry ingredients would not support the growth of microorganisms that might survive irradiation. The agency has no

information from which to conclude that flavors in liquid form can be irradiated safely. Also, the agency has no information indicating that processed flavors require treatment for disinfection. Anyone interested in pursuing this matter further may do so by submitting an appropriate food additive petition.

The agency agrees that a specific list of spices and seasoning agents is unnecessary. Collective terms are used to describe different groups of the minor ingredients and such terms may be more appropriate than a detailed listing. Although herbs may be used for both culinary and medicinal purposes, a food additive regulation applies only to the irradiation of culinary herbs. Therefore, the agency is now modifying the regulation to permit irradiation of dry or dehydrated aromatic vegetable substances: culinary herbs, seeds, spices, teas, and vegetable seasonings.

9. Some comments apparently assumed that the proposed regulation would not permit irradiation of spice blends and requested modification of the regulation to permit such irradiation.

The issue is twofold: (1) Whether blends can be irradiated, and (2) whether the regulation authorizes the irradiation of enough ingredients to make the irradiation of commercial blends practical. The regulation does not preclude the irradiation of spice blends. The agency recognizes that the limited number of spices listed in the proposed rule would have prohibited blends containing other ingredients. As explained above, the agency agrees that the description of the substances that may be irradiated as dry or dehydrated aromatic vegetable substances should be more comprehensive than that listed in the proposed rule. In addition, salt and other adjuvants or minor ingredients (such as anticaking and free flow agents) may be used in a blend of seasoning substances. Under such limited conditions of use, the irradiation of these minor dry ingredients would pose no concern. Therefore, the agency is describing in this final rule the spices and seasonings in general terms and is explicitly authorizing the use of blends of aromatic vegetable substances, as well as salt and other dry foods ordinarily used as minor ingredients in such blends.

3. Other Minor Foods

10. One comment stated that color additives are important ingredients in the manufacture of processed foods, as well as drugs and cosmetics, and are used in minute amounts in the diet. This comment further stated that turmeric and paprika are color additives that are also included in the list of spices and vegetable seasonings that can be irradiated and suggested that the final regulation be expanded to include other listed color additives.

The agency does not agree that this regulation should include color additives. In preparing its proposed rule, the agency had not considered the ramifications of approving the irradiation of color additives. Such consideration would include whether specifications established for a color additive based on current manufacturing processes would still be adequate for the color additive after irradiation and what doses would be needed to accomplish the intended effects. Persons able to document the safe use of a source or radiation to irradiate color additives may submit a petition to the agency. The agency agrees that turmeric and paprika are both spices and color additives. However, their major use is as seasoning agents, and the agency sees no reason to preclude irradiation of these aromatic vegetable substances when they are also used as color additives (Ref. 10).

11. One comment stated that the rule should allow for the irradiation of dry enzyme preparations for microbial disinfection at a dosage up to 30 kGy (3.0 Mrad) because they are minor food ingredients.

The agency had not considered this specific use of irradiation in developing the proposed rule. However, the agency received a petition to treat dry enzyme preparations at doses up to 10 kGy (1 Mrad), and in the Federal Register of June 10, 1985 (50 FR 24190), the agency amended § 179.22 to permit this use. In this document, the agency is deleting § 179.22 and is incorporating that authorization for irradiation of dry enzyme preparations in new § 179.26(b). Persons able to document the safe use of a source of radiation at dosage levels higher than 10 kGy (1 Mrad) as authorized in new § 179.26(b) to control microbial contamination in dry enzyme preparations may submit a petition to the agency.

4. Destruction of Nutrients

12. Several comments stated that destruction of nutrients should be a concern in this rulemaking. The comments stated that many vitamins are light or heat sensitive, and that irradiation will destroy them. One comment stated that nutritional problems may develop for consumers because of nutrient loss when an entire class of foods is irradiated.

The proposal discussed this issue and explained that the available literature indicated that there are no nutritional differences between unirradiated food and food irradiated at levels below 1 kGy (100 krad). The minor ingredients allowed to be irradiated at higher doses are not sources of nutrients. Therefore, the agency believes it is appropriate to conclude that destruction of nutrients is not an issue in this rulemaking. There have been no additional data submitted to change this conclusion.

5. Selective Destruction of Microorganisms

13. One comment indicated that irradiation could contribute to increased aflatoxin contamination of foods. The comment cited a series of studies published in 1978 and 1979 by researchers from the National Institute of Nutrition of the Indian Council of Medical Research which reported that wheat irradiated at dose levels up to 250 kilorads showed a dose-dependent susceptibility to aflatoxin production (Refs. 11 and 12).

The agency disagrees that irradiation would contribute to increased aflatoxin contamination of foods. The studies referenced do not replicate actual food-handling practices. In the studies, the wheat was irradiated, autoclaved, and then innoculated with an aflatoxin-producing organism. The agency has no evidence that would lead it to conclude that food irradiated and stored under normal handling practices would show increased aflatoxin production. FDA does not believe that the results cited justify a modification of this rule.

14. Several comments stated that irradiation intended to eliminate one food hazard may affect the microbial spoilage patterns of food, thereby creating a new hazard. These comments expressed concern that *C. botulinum* spores would survive irradiation and would produce botulinum toxin without typical signs of food spoilage.

The agency agrees that this is a legitimate concern in some situations, but it does not apply to irradiation of dry foods or foods irradiated below 1 kGy (100 krad). Irradiation of food below 1 kGy (100 krad) will destroy few spoilage bacteria and thus will not change normal spoilage patterns. Furthermore, irradiation of minor ingredients at high doses, as allowed in this rule, would pose no problems because these minor ingredients are dry and dry foods do not provide a growth medium for *C. botulinum* spores.

15. Some comments stated that food irradiation may create or produce potentially harmful radiation-resistant bacteria, new bacteria, or viral mutants. One comment raised the possibility that mutated deoxyribonucleic acid (DNA)

fragments might be incorporated by bacteria, viruses, or cells of the human digestive tracts to create other harmful mutants.

Mutants produced during the irradiation of food are essentially the same as those that occur naturally. The only real difference is in the rate at which mutations occur. Radiation may increase the frequency of mutations and thereby increase the rate of evolution in bacteria or viruses that would occur otherwise through natural evolutionary processes. However, there is no reason to expect that the resulting mutants would be different or more virulent than those created in nature (Ref. 13).

Because bacteria are highly evolved organisms, well adapted to their environment, the vast majority of mutations would tend to be detrimental for the organisms. Mutant organisms that are more radiation resistant than their parents may survive and be present in an environment exposed to frequent sublethal doses of radiation. 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.

Furthermore, the agency does not believe that such radiation-resistant bacteria or viruses, if they were produced, would be more resistant to other antibacterial agents. Although it is possible that specific conditions and indiscriminate irradiation might produce mutants, the agency concludes that the possibility that such mutants would be more virulent or more harmful is remote (Ref. 13).

There are only a few reports of genetic exchange between bacteria in the mammalian gut (Ref. 14). A few theories state that host cells may incorporate prokaryotic DNA, but it is not clear whether such genetic information is expressed. The agency sees no reason to prevent irradiation of food because of such speculations.

6. Toxicological Studies

16. Many comments claimed that it is FDA's first responsibility to ensure the absolute safety of all food produced and consumed in this country, not simply to make the process of production easier and/or cheaper for producers.

FDA agrees that its responsibility is to ensure that a food additive be demonstrated to be safe under the proposed conditions of use (21 U.S.C. 348(b)), but the agency does not believe that it was the intent of Congress, when formulating the act, that FDA ensure the consumer of absolute safety of all foods. Congress recognized that it would not be possible to determine with absolute certainty that no harm shall result from the intended use of a food additive. The Senate report stated: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." S. Rept. 2422, 85th Cong., 2d Sess. 8 (1958). As stated earlier, this is the standard of safety applied by FDA in its rulemaking for food additives.

On the other hand, the legislative history makes clear that Congress did not intend FDA to make regulatory decisions on the use of an additive based on an arbitrary opinion as to whether the additive should be used. Thus, the agency, in approving the use of a food additive, considers whether the food additive is safe and effective and not whether such approval will be beneficial to the producer of the additive.

17. One comment asserted that FDA's proposed regulation was illegal because it was not based on animal testing. While recognizing that neither the Food Additives Amendment of 1958 nor its legislative history specifies the exact types of tests that must be conducted to establish safe conditions of use of an additive, the comment claimed that a recurrent theme in much of the legislative history is the need for testing in animals to establish the safety of a particular additive.

The agency agrees that much of the testimony before enactment of the Food Additives Amendment of 1958 discussed animal testing of additives. This could be expected because most of the testimony about testing concerned direct food ingredients of unknown toxicity. Congress did not discuss how irradiation of food should be tested for safety. Furthermore, there is no indication in the legislative history that Congress expected every additive, whether an ingredient, a source of irradiation, or an incidental additive, to be tested the same way; nor does the act require such testing. Such a requirement would result in an unnecessary expenditure of resources. Consistent with this view, FDA has never required the same testing regimen for all types of additives.

FDA believes that the testing requirement envisioned by Congress was that there be sufficient testing to support the conclusion that there is a reasonable certainty of no harm from the expected use of the additive. The agency believes that any test that would not contribute to this conclusion should not be required. The agency has not required animal testing in the past under 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. Therefore, FDA concludes that available animal test data are not necessary for determining the safety of those uses of radiation encompassed by this document. Animal testing is too insensitive to show an affect from irradiation of food at the doses allowed and, thus, would not contribute additional information to the evaluation of the safety of such uses.

Nevertheless, the agency reviewed all available animal studies to determine their adequacy and to evaluate the toxicological evidence. FDA's evaluation of these studies comfirms the agency's earlier conclusions that such data would not contribute further assurances of safety of foods irradiated in compliance with this rule.

18. One comment stated that food irradiation should be presumed dangerous until adequate scientific information is available for responsible decisionmaking and that FDA should make no decision until more information on hazards versus benefits of food irradiation is available.

For reasons discussed earlier in this section, the agency has determined that adequate information on radiation chemistry of foods is available to conclude that foods irradiated in compliance with this regulation are safe, and that the intended effects are achieved, thus complying with section 409 of the act.

19. One comment was concerned about the reliability of studies where animals were fed an abnormal diet and stated that results from these studies, positive or negative, may be misleading.

The agency agrees that standard toxicology tests where large percentages of the diet are composed of a single food, either irradiated or otherwise, may give results that could be misleading. The major difficulty in toxicological testing of irradiated foods has been to design tests that would provide useful and meaningful information regarding safety. It would be difficult to design a test that would exaggerate greatly the level of radiolytic products that will be ingested from irradiated food because, to accomplish this, the amount of irradiated food—the test substance that will be ingested—may also need to be increased. This increase in dietary intake may not be tolerated and may thereby become an added stress to the animal. A substantial change in diet may also create nutritional imbalances

among either macro- or micronutrients of the diet.

FDA believes, however, that useful information has been learned from those feeding studies where there has been some exaggeration of dose relative to that prescribed by this regulation. This information together with knowledge of the chemical changes that occur at low doses of irradiation is sufficient to establish the safety of food irradiated in accordance with this regulation.

20. One comment suggested that FDA should require animal feeding studies in which the animals are fed food irradiated at exaggerated doses to obtain an adequate safety factor.

FDA acknowledges that food additives have typically been tested in animals at levels that greatly exaggerate the proposed levels of use of the additive to establish an adequate margin of safety. This traditional method of establishing a margin of safety is inappropriate when the additive is a source of radiation. FDA has examined many early studies in which food fed to animals was irradiated at exaggerated doses to determine the effect of ingesting increasing amounts of radiolytic products. The agency noted that treatment of food with increasing doses of radiation can destroy essential components (e.g., nutrients) of the food or make the food unpalatable. These factors can confound experimental results.

Because these effects on food do not occur at the lower doses, exposure of the foods to exaggerated radiation doses would not in these instances represent a valid test for determining the safety of foods irradiated at the levels of use prescribed by this regulation. The agency has, therefore, concluded that exposing food to ever increasing doses of radiation as a means of increasing the amount of radiolytic products ingested is generally not appropriate.

21. A number of comments objected to approval of irradiation of any fruit or vegetable because of reports that irradiated sucrose solution caused toxic effects. The comments suggested that sucrose solutions would serve as good models for evaluating the safety of irradiated fruits and vegetables and that the reported toxic effects were reason to disapprove this use of irradiation.

The agency agrees that irradiated solutions of sugars have been shown to cause biological effects in vitro. Certain studies have shown: (1) Abnormal anaphase formation in bean root tips treated with sucrose solutions irradiated at 2 Mrads (Ref. 15), (2) decreased growth in carrot tissue cultures grown in sucrose solution irradiated at doses ranging from 0.05 to 2 Mrad (Ref. 16), and (3) increased revertants in *S. typhimurium* after incubation with irradiated solutions of sucrose and irradiated solutions of glucose and ribose (Refs. 7 and 17). (The agency points out that its use of the term "sugar" in this response is generic. Where appropriate, specific sugars are mentioned by name.)

The biologically active compounds formed during irradiation of sugar solutions in the presence of oxygen are predominantly dicarbonyl sugars produced by reaction of peroxy radicals with sugar molecules. These dicarbonyl sugars can then be converted to *alpha, beta*-unsaturated carbonyl sugars which are also present in nonirradiated foods. The yield of biologically active carbonyl sugars will be less in irradiated complex food matrices than in irradiated simple sugar solutions because of reactions with substances such as metal ions and oxygen present in foods (Ref. 9).

The authors of the study using bean root tips (Ref. 15) postulated that the increased amount of abnormal anaphase was due to a drop in the pH of the irradiated sucrose solution. In a subsequent experiment reported in the same paper, the authors concluded that the low pH caused by irradiation of the sucrose solution alone was the cause of the mutagenic effects.

In feeding studies where sugars are present in a typically complex food matrix there is no increase in mutagenicity after irradiation. For example, direct irradiation of mango pulp to 20 kGy (2 Mrad) produced no mutagenic effect (Ref. 7). This study demonstrated that when a food containing sugars is irradiated, the food does not produce the same toxic effects that occur when these sugars are irradiated in simple solution. There is ample evidence (Refs. 7, 18, and 19) that the types and quantities of radiolytic products from irradiation of sugar solutions are not only dose dependent but are also dependent on specific conditions such as oxygen concentration and metal ions present in foods but not present in simple sugar solutions. Other studies on irradiated foods such as strawberries, dates, and mangoes likewise show no evidence of toxic effects (Refs. 20 through 26). The other studies that the agency reviewed regarding the toxicity of irradiated sucrose were of such poor quality that the agency does not believe that the data can be evaluated in a meaningful way.

The agency therefore concludes that irradiated aqueous sugar solutions are unsuitable models for predicting and extrapolating toxicity of irradiated foods. Therefore, the effects observed in these types of studies are not considered by the agency to be a reason for concluding that the uses of irradiation set forth in this regulation are not safe. The agency also concludes that there is no evidence that radiolytic products from sugars present in irradiated foods cause toxic effects to animals or humans.

22. One comment stated that a report in *Nature* magazine (Ref. 16) indicates that eating sugars irradiated at doses ranging from 0.05 to 2 Mrad can produce the same genetic changes in humans as exposure to irradiation itself.

The agency has reviewed this study and disagrees with the comment's interpretation of what the study found. Indeed the authors clearly did not reach the conclusions attributed to them by the comment. Furthermore, if humans or animals were irradiated at doses even 1,000 times lower than the levels used in this study, not only sterility but lethality would result within hours. On the other hand, humans and animals have consumed food irradiated at up to 4 Mrads (Refs. 27 through 32) without any indication of adverse effects of any kind. The study the comment referred to involved the effects of radiation on carrot tissue in liquid culture irradiated at 20 kGy (2 Mrads). This study and others concerning the effects of irradiation on solutions of sugars were discussed in the response to the previous comment.

The agency recognizes that irradiated sugar solutions have produced toxicity in vitro. The agency concludes, however, that irradiated sucrose solutions are unsuitable models for predicting and extrapolating toxicity of irradiated foods. Additionally, no evidence indicates that irradiated foods, including those containing sugars, will cause adverse toxic effects to animals or humans.

23. A few comments stated that a study involving hundreds of thousands of humans over 20 or 30 years is necessary before FDA can say irradiated foods are safe.

The agency has never required such long-term testing in humans to approve the use of a food additive and disagrees that such a study is necessary or appropriate. The agency recognizes that it cannot say with absolute certainty that any food, irradiated or not, is absolutely safe for all people under all conditions. The agency believes that the differences between foods irradiated as prescribed by this regulation and nonirradiated foods are so small, particularly compared to normal variations in the diet, that no effect is expected to be observed. The agency

believes that the substantial amount of available toxicological information supports the conclusion that the irradiation of food, as set forth below, is safe. Therefore, there is no basis for delaying for decades a decision to regulate food irradiation to conduct the type of study suggested by these comments.

24. Some comments also stated that many of the long-term toxicity studies on food irradiation were performed by Industrial Bio-Test Laboratories (IBT) and should, therefore, be considered invalid because much of the data generated by IBT had been falsified.

FDA agrees that studies containing falsified data performed by IBT should be rejected. All studies identified in the agency's review of available toxicological literature on food irradiation that had been performed by IBT were rejected. Much of the data compiled by IBT had been falsified or were proven invalid due to flaws in data collection, data reporting, and/or in experimental design. Thus the agency considers such data unacceptable to support safety.

25. Several comments stated that there are only a limited number of adequate chronic feeding studies on irradiated foods and that testing of the long-term health effects of consuming irradiated foods has been inadequate.

The agency has determined that because only minor chemical changes may result in food treated with low doses of radiation, animal feeding studies are not necessary to establish the safety of foods irradiated under conditions prescribed by this regulation. Therefore, it believes that the number of adequate chronic feeding studies on irradiated foods is irrelevant to its safety conclusion. The agency has evaluated those chronic studies that have been properly conducted and are considered to be adequate by current standards. None of those studies show adverse effects from the ingestion of irradiated food.

7. Alleged Adverse Effects

The agency reviewed 441 toxicity studies on irradiated foods (Refs. 2, 3, and 4). Forty-five of these studies dealt with subacute toxicity, 58 with subchronic toxicity, 128 with reproductive toxicity, 14 with teratology, 110 with chronic toxicity, and 102 with genetic toxicity or irradiated foods. Only 5 of the 441 studies reviewed (3 chronic feeding studies (Refs. 20, 33, and 34), 1 reproduction study (Ref. 35), and 1 combined chronic, reproduction, and teratology study (Refs. 36, 37, and 38) were considered by agency reviewers to be properly conducted, fully adequate by 1980 toxicological standards, and able to stand alone in the support of safety. The reports of these five studies indicate no adverse effects from the irradiated foods fed to test animals.

Although most of the studies were generally inadequate by present day standards and could not stand alone to support safety, many contained individual components which, when examined either in isolation or collectively, allowed the conclusion that consumption of foods treated with low levels of irradiation did not appear to cause adverse toxicological effects. 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 have seen no such effects that present consistent patterns or trends of adverse effects that might be attributable to exposure to food irradiated at low dose levels. The agency, therefore, concludes that irradiation of foods as prescribed by this regulation is safe.

26. One comment referenced a book, "Consumer Beware" by B. Hunter, which stated that rats fed irradiated bacon and irradiated bacon and fruit mixtures showed increased mortality and an increased incidence of tumors. The author stated that the tumor incidence was increased and longevity was decreased.

Summaries of these studies were submitted in an early petition for sterilization of bacon by irradiation. FDA originally issued a regulation based on this petition (28 FR 1465; February 15, 1963). However, following evaluation of the complete reports of this study, FDA concluded that the sponsor had not met its burden for demonstrating safety (33 FR 12055; August 24, 1968) and rescinded the bacon regulations (33 FR 15418; October 17, 1968). Although previous reviewers asserted that the irradiated bacon studies may have shown adverse effects, the agency, after extensive reexamination of the study, now concludes that the claimed adverse effects cannot be substantiated because: (1) The study was of poor quality, (2) the numbers of animals examined were too small (three rats per group per generation) to have any statistical significance concerning tumors or longevity, and (3) the "total" incidence was only slightly increased in the low-dose group with no apparent dose dependence. Most national and international scientific bodies do not consider an increase in total tumors appropriate criteria indicative of a carcinogenic response (Ref. 40). The important consideration for determining if there is a carcinogenic response is whether there is an increase in the number of tumors at a specific organ site. The Armed Forces Institute of Pathology report (Ref. 39) on this study maintained that the tumors "showed no predelliction for any single organ." The numbers of animals at risk were too few to conclude that there was an effect on tumor incidence or longevity. If such effects had been caused by irradiated bacon, they should have been reproduced in the other irradiated feeding studies, including those the agency considers properly conducted (Refs. 20 and 33 through 38). However, such adverse effects were not observed.

27. One comment referenced a statement in the book "Eating May be Hazardous to Your Health," by J. Verrett and J. Carper that "[i]rradiation at high levels has been shown not only to severely destroy vitamins and minerals in food, but also to cause reproductive problems, a shortening of the life span and other complications in laboratory animals. In some instances—for example, in irradiated jams and fruit compote—cancer is a suspected result." The comment also stated that Dr. Verrett was a biochemist and researcher with FDA for 15 years.

The agency agrees that irradiation at high dose levels has been shown to destroy vitamins and other nutrients in food. As discussed in paragraph 11 of this preamble, however, destruction of nutrients is not a public health problem under the conditions of use approved for sources of radiation by this regulation.

It is not entirely clear which studies the authors were referring to in the statement from their book. The agency acknowledges that Dr. Verrett was an FDA employee during which time she reviewed many of the early petitions on food irradiation. The agency has reevaluated her reviews of the studies contained in these petitions. Judging from the irradiated foods mentioned in the statement quoted from her book and in the memoranda in the petitions, it appears that she is referring to two studies in which rats were fed a diet of (1) irradiated bacon and fruit compote (mixtures) (Ref. 39) and (2) irradiated pork, peaches, jam, carrots, and flour (Ref. 41).

The longevity and tumor (cancer) questions referred to in study 1 are addressed in paragraph 26 of this preamble. The agency has stated that an increase in "total" tumors is not indicative of a carcinogenic response by modern criteria for judging

carcinogenicity and the numbers of animals at risk were too low to conclude that there was either a tumor or longevity concern.

During its evaluation of toxicology data in 1982, the Task Group listed reasons for difficulty in evaluating the reproduction data from this study. The reasons include: (1) Inconsistent reporting of the numbers of animals used in each replicate experiment in several summary tables, (2) stillborn animal data not reported for every generation, (3) number of pregnant females not reported for all generations, (4) number of litters cannibalized only reported for the parental generation, (5) no indication given as to how or from which litters subsequent generations were chosen, and (6) replicate experiments not consistently identified in the summary tables.

In the second study (Ref. 41), the authors stated that there was a higher growth rate in the 2d and 3d generation animals and inferior breeding performance. Dr. Verrett was also concerned with reproductive and longevity questions in this study. FDA's reevaluation of this study cannot support Dr. Verrett's claims because the study was of very poor quality. The study pathologist specifically detailed many of the study's shortcomings and stated in the final report that "any conclusions resulting from this work should be drawn from the overall picture rather than the detailed studies of isolated aspects or organs" (Ref. 41).

The agency agrees with the pathologist's statement and has attempted to evaluate the overall picture referred to by the pathologist. As stated earlier, 5 animal feeding studies (Refs. 20 and 33 through 36) concerning longevity and/or reproduction (out of 441 toxicological studies reviewed) were considered by agency reviewers to be well designed, properly conducted, and reported. The reports of these five studies indicate no adverse effects to test animals fed irradiated foods.

The agency review included reports of 44 chronic studies, 60 reproduction studies, and 68 combined chronic reproduction studies. Although most of these studies have been considered less than adequate for a variety of reasons, the agency has been able to conclude from them collectively that no treatment-related adverse effects on the longevity of test animals or their reproduction were evidenced by these studies.

28. One comment referenced the report of a study (Ref. 42) in which statistically significant changes in the weights of ovaries and testes were observed when irradiated onions were fed to mice.

FDA has evaluated the report of this multigeneration reproduction study and notes that it was only an abstract from the World Health Organization (WHO) and has never been published as a complete report. The effects reported were a decrease in ovarian weight, significant when compared to both the normal control (no onion diet) and the onion control (unirradiated onion diet), and a decrease in testes weight significant as compared with the normal controls only. Histological examination did not reveal any particular changes in the ovary and testes of the group fed irradiated onions. No effects were observed on reproduction, fertility, or other parameters observed. In 1977, a WHO committee reviewed a draft of the manuscript and reported that because there were no observed abnormal histopathology changes or deleterious effects on reproduction, these organ weight changes, if real effects, were not regarded as being treatment related. Other reproduction, subchronic, or chronic studies on irradiated onions (Refs. 37 and 43 through 47) at comparable or higher doses of irradiated food administered to other animals did not report any changes in ovarian or testicular weights. These findings lead the agency to agree with the conclusions of the WHO committee.

29. One comment, citing a review paper (Ref. 48), stated that "when dogs have been fed irradiated egg solids, reproductive failure has occurred, and chicks and rats have died as the result of hemorrhage due to lack of vitamin K."

This statement has been taken out of context. The authors were actually referring to the nutritional imbalances seen in some of these irradiated food studies. The entire quote reads:

> Despite the fact that the experimental animals are provided with diets of known nutritional requirements for adequate growth and development, the high level of test food which is incorporated in the diets may present a completely unrealistic situation which can place a nutritional stress on the animals and result in nutritional imbalances. An example of this situation has been observed in feeding of high levels of irradiated egg solids to dogs where the interrelationship between biotin and avidin was found to exert a role in causing reproductive failure. A related example of difficulty which has been experienced in separating potential toxicity and nutritional adequacy of irradiated foods was the previously mentioned effect of radiation sterilization on vitamin K (an hemorrhagic factor) in certain foods, which resulted in hemorrhage and death in chicks and rats. Careful and detailed studies are necessary to elucidate the mechanisms involved in physiological abnormalities of this nature.

FDA agrees with the authors that nutritional imbalances resulting from feeding large amounts of a single food to animals confound the results of these studies.

30. One comment stated that polyploidy (chromosomal changes) has been shown as a toxic consequence in animals and humans fed irradiated wheat.

The agency does not believe that this is a correct statement. The agency is aware that in several experiments conducted by the National Institute of Nutrition (NIN), Indian Council of Medical Research, Hyderabad, India, the investigators claimed that polyploidy (chromosomal changes) was a toxic consequence in animals and humans fed irradiated wheat. A committee of Indian scientists critically examined the techniques, the appropriateness of experimental design, the data collected, and the interpretations of NIN scientists who claimed that ingestion of irradiated wheat caused polyploidy in rats, mice, and malnourished children. After careful deliberations, this committee concluded that the bulk of these data are not only mutually contradictory, but are also at variance with well-established facts of biology (Ref. 49). The committee was satisfied that once these data were corrected for biases which had given rise to these contradictions, no evidence of increased polyploidy could be associated with ingestion of irradiated wheat.

The agency agrees with the conclusions of the committee of Indian scientists that the studies with irradiated foods do not demonstrate that adverse effects would be caused by ingestion of irradiated foods.

31. One comment disagreed with FDA's conclusion that foods irradiated at doses below 1 kGy (100 krad) are safe and stated that there is little reassurance in the fact that unidentified radiolytic products are present in irradiated foods at low concentrations, particularly if single exotic molecules may be capable of causing carcinogenic chromosomal aberrations.

The agency recognizes that radiolytic products will be formed in irradiated food. Ionizing radiation results in the formation of unstable free radicals and other reactive chemical intermediates which normally undergo rapid reaction to form more stable molecules. Of the total radiolytic products formed, a small fraction may be assumed to be unique or "exotic." Radiolytic products and URP's have been defined both earlier in this section and in the BFIFC report (Ref. 1). Certainly some URP's will be formed

which are structurally atypical of parent food molecules. Such URP's may be free radical coupling products of lipid and protein-derived radicals, dimers, and cross-linked products. However, enzymatic hydrolysis of some of these compounds by normal digestive enzymes is expected to yield normal molecular subunits such as fatty acids, amino acids, monosaccharides, and normal metabolic products of these subunits which would be the same result as from the normal digestion of the original parent molecules.

If exotic molecules of the extreme toxicity implied by the comment were present at any level of toxicological significance in irradiated foods ingested by test animals, some consistent toxicological trends and patterns would be manifest in the studies reviewed. Because it has seen no consistent trends or patterns, the agency concludes that foods irradiated as prescribed by this regulation are safe.

32. One comment referenced a study submitted to FDA by USDA on fruit flies (drosophila) fed irradiated chicken. This study showed a dose-related decrease in offspring (Ref. 50), and the comment stated that this effect is consistent with chromosmal damage.

FDA notes that in the sex-linked recessive lethal study in Drosophilc there was no evidence of mutagenicity. Additional data on fertility and fecundity were also included in the study, and a dose-related decrease in offspring was noted. Although there were fewer offspring in the groups raised on irradiated diets than in concurrent controls, the agency concluded that this effect could arise from a host of causes unrelated to reproductive toxicity, and is an unreliable indicator of an adverse reproductive effect. Mammalian data on reproduction are more relevant to humans, and these studies, as stated earlier, demonstrate no consistent patterns or trends indicative of a positive reproductive effect.

33. One comment referenced a study submitted to FDA by USDA and stated that mice fed radiation-sterilized chicken meat showed a significant increase in testicular tumors, increased death rate, increased kidney damage (glomerulonephropathy), and decreased survival. In addition, the comment implied that male dogs fed radiation-sterilized chicken had significantly lower body weights throughout adulthood than dogs fed a frozen control diet, and claimed that this shows toxicity of the irradiated chicken diet.

The agency disagrees with the comment that these studies demonstrate a treatment-related increase in testicular tumors. The studies involving mice and dogs fed radiation-sterilized chicken were carried out at Raltech Scientific Services (Raltech). These studies were initiated under the sponsorship of the U.S. Army and completed under the sponsorship of USDA.

The report prepared by Raltech scientists suggested the possibility that chicken irradiated at approximately 6 megarads produced testicular tumors in CD-1 mice in lifetime feeding studies (Ref. 51). Agency scientists have independently examined the histopathology slides to determine whether testicular tumors were induced by ingestion of irradiated chicken. They concluded that the total histopathological evidence did not support a treatment-related induction of testicular tumors (Ref. 5).

These data were also referred to the National Toxicology Program's Board of Scientific Counselors for peer review. The Board concluded also that the data do not allow the study to be categorized as one demonstrating a carcinogenic response in mice fed chicken meat treated with gamma or electron beam radiation (Ref. 6).

All mice fed chicken meat diets (both nonirradiated frozen chicken meat control diets and irradiated chicken meat diets) showed signs of extensive mineralization and glomerulonephropathy and decreased survival compared to mice fed chow control diets. After careful examination of the studies and comparison of data between the mice fed chicken meat control diets and the mice fed chow control diets, the agency concludes that the effects were due to the high protein content of the chicken diets rather than to the fact that some diets were irradiated.

The agency noted decreased survival in the female mice of the group fed gamma-irradiated chicken. However, because the decreased survival occurred only in one sex group, and the result was only marginally significant ($p = 0.04$), the agency does not consider this effect to be treatment related.

With regard to the dog feeding study, the agency does not consider the body weight decrease to be of toxicological significance because of the nature of the protocol that was followed. The maximum quantity of diet provided for each dog was originally limited to 500 grams per day (approximately 300 grams dry matter per day). However, some dogs fed chicken meat diets (irradiated, frozen, or thermally processed) consistently consumed the entire daily ration and consequently had higher body weights than dogs fed chow control diets. This difference in body weights between the different diet groups is attributable to excessive caloric intake of the dogs fed chicken meat. Assuming that the dogs should maintain an "ideal" weight, the contract laboratory restricted the food intake for "selected" overweight dogs as required to initiate weight loss until acceptable body weights were obtained. The few dogs considered underweight were allowed to feed until their body weight increased to an acceptable level. Because the diet was manipulated in this way, the agency does not consider the changes in body weight to be treatment related.

34. Several comments referenced two Russian reports (Refs. 52 and 53) that found damage to kidneys and testes in rats fed irradiated feed. The authors reported dose-dependent histopathological changes in the kidney and testes of rats fed irradiated lab-chow. The changes were claimed to be similar to those changes seen in human autoimmune disease involving these tissues.

FDA has found that information on critical details of the experimental design of the studies is either incomplete or missing. The reproductions of photomicrographs are unusable, and the numerical data are incomplete across dosage groups. There is no information on the survival rates of rats to the end of the experiment. The total number of rats actually examined for histopathologic observation is not stated nor is the scope of such observations. There is a general lack of incidence values and survival information that are critical for interpreting the findings in the kidneys and testes.

The agency notes that the authors had not published any previous studies in which rats were used as experimental models and, therefore, these authors may not have been familiar with common progressive nephrosis of the rat kidney. The qualitative description of the kidney changes reported is generally consistent with kidney disease commonly seen in aged laboratory rats. Many of the features of chronic progressive nephrosis (Ref. 54) common to aged rats are identical with the microscopic changes described in kidneys by the Russian authors. Without information on the comparative incidence and severity of the kidney lesions in all groups, the agency cannot verify that these reported effects are treatment-related, especially considering the inevitability of these types of kidney changes in rats as a result of old age.

FDA reviewed the kidney data in 11 chronic studies (Refs. 28, 33, 34, 55 through 62) in which rats were fed

various diets consisting of food or feed irradiated at various doses under a variety of conditions to see if it would be possible to confirm the findings of the Russian authors. An examination of these results revealed no findings or evidence of treatment-related kidney changes as were reported by the Russian authors. One of the 11 studies reviewed, which most closely resembled the Russian study (Ref. 28), had also investigated rats fed a diet consisting wholly of chow irradiated at both a lower (2 kGy, 0.2 Mrad) and higher (25 kGy, 2.5 Mrad) dose. The agency reviewed this study and found no evidence of treatment-related kidney changes as reported in the Russian study.

Further, the treatment-related kidney effects claimed by the Russian authors have not been reported in any other mammalian studies as an effect caused by ingestion of irradiated food. Also, data available on irradiation of animal feeds where the whole animal diet is irradiated have not shown comparable pathology (Ref. 27).

Based on the descriptions of the findings of testicular effects, FDA believes that such findings are probably not induced by radiolytic products in the irradiated diet. Extreme size and weight differences between right and left testes can arise from trauma (e.g., fighting) or may be present from birth. It is not clear whether some of the microscopic changes that are discussed affected both testes or were a feature of the smaller testes. FDA also reviewed 11 studies to verify the testicular lesions reported by Russian authors, and none of the studies reviewed revealed treatment-related testicular changes similar to those reported in the Russian reports. One of the 11 studies reviewed, which most closely resembled the Russian study (Ref. 28), found no evidence of treatment-associated testicular changes similar to those reported in the Russian study.

The agency concludes that, given the paucity of data from these two reports and the considerable, more substantial, evidence from other studies, the results of these Russian reports do not raise valid questions concerning the safety of food irradiated under the conditions of this regulation.

35. One comment claimed that three reports showed dominant lethal effects of irradiated foods (Refs. 63, 64, and 65).

The agency has reviewed these studies, and two of these three studies have been addressed (Refs. 64 and 65) in the response to paragraph 30 of this preamble. The third study (Ref. 63) claimed to have demonstrated an increase in preimplantation deaths. In this study, mice were fed 50 percent of their standard chow diet irradiated at a dose of 50 kGy (5 Mrad). There was no increase in postimplantation losses. Postimplantation losses, determined by counting dead embryos, are believed to be the most reliable and sensitive indicator of dominant lethality. The authors found only preimplantation losses, which are much less sensitive than postimplantation losses and merely a measure of total implants dead or alive subtracted from the total number. In addition to the possibility that results of the study could be spurious, any number of factors other than dominant lethality may cause preimplantation losses, such as a decrease in the number of eggs ovulated.

If these effects were real, one would expect to see some effect on postimplantation losses at a lower dose because postimplantation losses are a much more sensitive indicator than preimplantation losses, as mentioned above.

Although the findings reported may be statistically significant, the authors were uncertain as to what to attribute these results. They concluded that the most probable mechanism by which these effects could be produced would be via chromosomal aberrations. The studies necessary to establish an association between these effects and chromosomal aberrations were not conducted. Additional treatment levels below that conducted as mentioned above to detect postimplantation losses or examination of the 24 to 48 hour fertilized eggs could have provided better evidence of causality; but these studies were not conducted. Thus, although preimplantation losses were observed, FDA concludes that there is no biological significance to this observation because it was not reproducible. In three comparable studies, two in mice and one in rats (Refs. 66, 67, and 68), where 100 percent of the chow diet was irradiated with 25 kGy (2.5 Mrad) giving comparable radiolytic products as those found in Ref. 63, no preimplantation losses were demonstrated.

B. Labeling Issues

Under current regulations (21 CFR 179.22 and 179.24), several specified foods are permitted to be irradiated provided that the label bears the following statements: (1) "Treated with ionizing (or gamma or electron) radiation" on retail packages, or (2) "Treated with ionizing (or gamma or electron) radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments. In the proposal, FDA stated that it was interested in receiving additional comments discussing: (1) Whether FDA should require any type of label statement on food that has been irradiated; (2) if so, whether the statement should be required only on labels of food that has been irradiated (first generation foods) or also on the label of finished foods which may contain irradiated ingredients (second generation foods); (3) whether any required label statement should remain the same as that provided under existing regulations (i.e., "treated with ionizing (or gamma or electron) radiation") or whether some other phrasing would be more appropriate (e.g., "processed with ionizing energy"); and (4) whether consumers would be more misled by the presence of some type of retail label statement or by the absence of such a statement.

The labeling provisions of this final rule differ from that in the proposed rule and from the current labeling regulations as follows: This regulation requires that the wholesale label bear either the statement "Treated with radiation, do not irradiate again," or the statement "Treated by irradiation, do not irradiate again," and that the retail label bear the following logo:

along with either the statement "treated with radiation," or the statement "treated by irradiation." Throughout the remaining discussion in the preamble about the labeling provisions, the agency has used the terms "treated with radiation—do not irradiate again," and "treated with radiation," to represent both alternatives that the manufacturer may use in its wholesale or retail labeling in order to simplify the discussion. In addition to the mandatory language, the manufacturer may also state on the wholesale or retail label the purpose of the treatment process or expand upon the kind of treatment used. That is, the manufacturer may include in the labeling any phrase, such as "treated with radiation to control spoilage," or "treated with radiation to extend shelf

life," or "treated with radiation to inhibit maturation" as long as the phrase truthfully describes the primary purpose of the treatment. Similarly, the manufacturer may choose to state more specifically the type of radiation used in the treatment, i.e., "treated with x-radiation," or "treated with ionizing radiation," or "treated with gamma radiation," if more specific description is indeed applicable.

The agency recognizes that, because this is a new technology, manufacturers may want to use additional labeling statements as part of a consumer education effort. For example, in addition to the required language, the firm may wish to state that "this treatment does not induce radioactivity." The agency will permit such educational statements if they are truthful and not misleading to consumers.

In lieu of labeling individual items of unpackaged irradiated foods, FDA is allowing the required logo and label to be displayed to the purchaser as a point-of-purchase counter sign or card or on the labeling of the bulk container.

Half the comments specifically addressed the retail labeling issue, and over 80 percent of those comments urged that retail labeling be "required to prevent consumer deception." The remaining comments opposed any retail labeling of irradiated foods. Most comments, however, were in favor of some sort of labeling for wholesale packages of foods still in processing to prevent reirradiation.

In addition, the large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers. Moreover, several comments argued that irradiation of food altered the organoleptic properties of food, thereby reducing its nutritional value. These changes in the food, the comments asserted, make the irradiation of the food a material fact that must be disclosed under section 403(a) and 201(n) of the act. Because of these comments, FDA had decided to require that the label and labeling of food products bear the appropriate statements to inform consumers that the food has been irradiated. The agency emphasizes, however, that the labeling requirement is not based on any concern about the safety of the uses of radiation that are allowed under this final rule. Further responses to these comments are contained in paragraphs 38 through 49.

38. One comment stated that FDA did not have the authority to require a retail label statement on foods that had been irradiated because such labeling was not a prerequisite for safe use under section 409(c)(1) and (d) of the act. This comment argued that where safety is not at issue, FDA's authority to require special labeling is much less expansive. This comment also stated that if the standard for misbranding under section 403(a)(1) of the act is whether an additive affects organoleptic properties of food (i.e., taste, color, smell, or texture of foods), the presence of many additives now commonly used in foods should be highlighted on current product labels because most additives affect these qualities to some degree. This comment also stated that conventional food-processing methods also affect the organoleptic properties of food.

The agency is of the opinion that there is adequate statutory authority under sections 403(a), 201(n), and 409 of the act to require a retail label statement on foods that have been irradiated even though there is no concern about the safety of such treatment at the doses provided by this final rule. Section 409(c)(3)(B) of the act prohibits the approval of a food additive if a fair evaluation of the data before the Secretary "shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act." In this case, the standard for misbranding under sections 403(a) and 201(n) of the act is whether the changes brought about by the safe use of irradiation are material facts in light of the representations made, including the failure to reveal material facts, about such foods. Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.

Food ingredients, including food additives that have a functional effect in food, are required to be disclosed on food labels. Food additives such as aspartame that are present as ingredients in foods are required to be included on the ingredient labeling statement on the food's label. Therefore, the consumer is informed of the presence of these ingredients and the representation is not misleading.

The agency agrees that conventional food-processing methods also affect the organoleptic properties of food in material ways but in these cases the processing is either obvious to the consumer or conveyed to consumers through labeling or packaging. Canned foods have obviously been canned and frozen foods have obviously been frozen. Pasteurized milk is not obviously pasteurized but this fact is declared on the label.

Canning, freezing, and pasteurization are, of course, well-established processes with which the consumer is familiar. Whether information is material under section 201(n) of the act depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer. The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers.

FDA has historically required the disclosure of a food processing agent whenever it is material to the processing of foods. For example, flour is required to be modified by the term "bleached" if bleaching agents are used in processing and modified by the term "bromated" if potassium bromate is used in the processing of the flour. These requirements are part of the standard of identity for various flours (see 21 CFR 137.205).

There are many other examples where processing must be disclosed. Several standards of identity require label disclosure if the product has been enriched or fortified (see 21 CFR 137.305, enriched farina). Several standards of identity for juices require that the label indicate when the product is made from a previously concentrated ingredient (see 21 CFR 146.145, orange juice from concentrate). Orange juice must also be labeled pasteurized when pasteurization is part of the juice's processing (see 21 CFR 146.140, pasteurized orange juice).

Foods made in semblance of a traditional food must disclose the processing difference. Potato chips made from dehydrated potatoes, onion rings made from minced onions, and fish sticks made from minced fish are all required to disclose these material differences in processing.

The agency concludes that requiring a retail label statement that a food has been irradiated is consistent with the agency's statutory authority and current labeling practice.

37. Several comments argued that a retail label requirement was inappropriate because irradiation was used in place of chemical fumigants and FDA does not require that these chemicals be identified on the retail label. One comment stated that "there is no more rational basis for labeling irradiated foods (at the retail level) than for labeling pesticide residues present in agricultural commodities, indirect additives from packaging, flour and bread from fumigated wheat, or the

current fumigated spices themselves." Another comment pointed out that FDA has long held the position that nonfunctional secondary additives need not be declared on the label and that the policy codified at 21 CFR 101.100 should apply to foods that have been irradiated.

The issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception. As stated earlier, irradiation may change the characteristics of a food in a manner that is not obvious in the supermarket. Packaging materials and incidental additives such as processing aids that have no technical or functional effect in the food and thus do not ordinarily affect the characteristics of the food may be exempted under 21 CFR 101.100 from the normal labeling requirements under the act. Furthermore, Congress specifically exempted pesticide chemicals under section 403(1) of the act from a retail labeling requirement when the food has been removed from its shipping container.

As stated earlier, FDA believes that the irradiation of food is a material fact that must be disclosed. The agency recognizes, however, that the irradiation of one ingredient in a multiple-ingredient food is a different situation, because such a food has obviously been processed. Consumers would not expect it to look, smell, or taste the same as fresh or unprocessed food, or have the same holding qualities. Therefore, FDA advises that the retail labeling requirement applies only to food that has been irradiated when that food has been sold as such (first generation food), not to food that contains an irradiated ingredient (second generation food) but that has not itself been irradiated.

38. One comment stated that a retail label requirement would imply that there is a hazard involved in radiation processing and that such a statement would mislead the public about the safety of the process and have a negative impact on the development of this technology.

Although FDA recognizes the potential for consumer confusion, because there is no safety problem with food irradiated in accordance with this final rule, any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs, and the presence of a retail label statement should not deter the development of this technology. Consumer comments reflect a growing awareness of the process of food irradiation. Many consumer letters acknowledge that food irradiation, as prescribed by the proposed regulation, will not cause the food to become radioactive. The agency has also received comments stating that experiences in other countries, such as the Netherlands, demonstrate that consumers do not necessarily reject irradiated foods when they are properly labeled.

A recent Good Housekeeping Institute Survey seems to support this view (Ref. 69). In addition, elsewhere in this document the agency has made it clear that manufacturers have the option of providing additional labeling to describe the specific purpose of the treatment provided that such additional labeling is truthful and not misleading.

The agency has also concluded, however, that the original labeling terminology required by existing 21 CFR 179.22 and 179.24 may be overly technical and that the type of radiation being used is not necessarily meaningful to consumers and that the retail label would be just as informative if the required retail statement were "treated with radiation." The regulation has been modified accordingly.

39. Other comments suggested that the retail label statement be revised to state: "treated with ionizing radiation to prolong shelf life to ——— (insert date)."

As explained above, any confusion created by the terms "radiation" or "irradiation" required to appear as part of retail labeling can be corrected by appropriate consumer education programs. 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 or the purpose of the treatment. Such additional explanatory language may be used whenever the additional language is applicable and not misleading.

For example, "treated with radiation to control insect infestation," "treated with radiation to inhibit maturation," and "treated with radiation to inhibit spoiling" are all examples of acceptable alternatives describing the purpose of the treatment if in fact the additional statements reflect the purpose of the treatment. "Treated with electron beam radiation" is an example of an acceptable expansion on the kind of treatment, if in fact an electron source was used. These optional statements would not only have an educational benefit, but would also avoid any possible mistaken inference by the public that the required labeling is a warning statement.

A manufacturer who wishes to label its product as "treated with radiation to extend the shelf life to ——— (*insert date*)" would, of course, be required to possess data substantiating that the radiation treatment would, in fact, extend shelf life until that date.

In addition, a manufacturer who finds that the terms "treated with radiation" or "treated by irradiation" are misinterpreted by a significant number of consumers may petition FDA for approval of alternative language, e.g., "freshness preserved by irradiation." However, the manufacturer would be required to provide adequate evidence demonstrating that the alternative language is both more readily accepted by the public and not misleading as to the nature of treatment as a form of radiation.

40. Several comments took the position that food irradiation is a food-preservation process and should be considered a process instead of a food additive, at least for labeling purposes. Those supporting this view stated that other food processes are not required to be revealed on the label and that food irradiation should be similarly exempt from label declaration. The comments also stated that a retail label statement is not justified on the basis of risk.

The agency agrees that irradiation uses permitted by this final rule are safe. The retail label requirements of existing 21 CFR Part 179 were based on misbranding considerations and not on food safety or health risk considerations. As has been explained before, section 201(s) of the act specifically includes a source of radiation as a food additive (21 U.S.C. 321(s)).

Nor is there any statutory provision that exempts processes from being declared on a food label (49 FR 5718) and the agency must examine whether the failure to declare such processing is misleading to consumers. In this context it is not relevant whether irradiation is considered a process in determining whether retail labeling is appropriate.

41. Most comments written in support of a retail label requirement for irradiated foods stated that the irradiation process has not been demonstrated to be safe, and that if irradiation treatment of food is permitted, the food label should inform consumers about which foods have been irradiated so that consumers can make informed decisions about the kinds of foods they buy.

As discussed elsewhere in this document, the agency has concluded that the irradiation of foods at a maximum dose of 1.0 kGy (100 krad) is safe when used to control arthropod pest infestation or to inhibit the growth and maturation of fresh foods. In view of this fact, the arguments in favor of a

retail label requirement based solely on the grounds that the irradiated food is not safe, must be discounted.

42. Several comments in favor of a retail label requirement argued that irradiation of food altered the organoleptic properties of food and reduced its nutritional value and that these changes are material facts requiring disclosure under sections 403(a) and 201(n) of the act. The comments stated that consumers have a right to know whether such processing has taken place.

A food is considered misbranded under section 403(a) of the act if its labeling is false or misleading in any particular. In determining whether labeling is misleading, the agency must take into account the extent to which the 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 (section 201(n) of the act). Therefore, the agency must decide whether the changes in the organoleptic properties of irradiated foods constitute a material fact or whether the information that a food has been irradiated constitutes information that is material to a consumer even if the organoleptic changes were not significant.

The agency agrees that irradiation causes certain changes in foods and that even small changes that pose no safety hazard can affect the flavor or texture of a food in a way that may be unacceptable to some consumers. Even those opposed to a retail labeling requirement agree that under certain conditions irradiation causes substantial changes in the organoleptic properties of some foods. Moreover, as discussed in the response to comment 36, irradiation may not change the food in any way that is visible to the consumer, so a label statement provides the only means of letting consumers know that a food has been irradiated. Thus, the absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed. Therefore, this regulation provides that the retail label contain a statement that the food has been irradiated.

43. The agency has also reviewed comments that argue both for and against the substitution of the term "ionizing energy" for the term "ionizing radiation" in the proposed wholesale labeling requirement and in any retail labeling requirement that was contemplated but not proposed. Most of the arguments for the substitution stated that they favored use of the term "ionizing energy" to reduce the problem of confusing irradiation with radioactivity and argued that use of the term "ionizing energy" would be less likely to be misunderstood by consumers. Other comments argued that both terms are likely to be misunderstood by consumers.

In view of the fact that the term "energy" could be confused with its more ordinary meaning as applied to foods, namely, a capacity of the food to provide caloric energy, the agency does not agree that substitution of the term "ionizing energy" would be less likely to be misunderstood by consumers. Furthermore, none of the comments offered any substantive evidence that one term would more likely be understood than another, either at the wholesale or retail level.

The agency does recognize that some population groups may harbor a prejudice against anything treated with radiation but is of the opinion that with the labeling flexibilities provided in this regulation, manufacturers will be able to overcome these prejudices as consumers become more educated about the process and the advantages this technology has over alternatives existing in the industry.

44. One comment suggested that the agency use the term "picowave treatment" in order to parallel the term "microwave treatment" that is commonly used for another form of food processing.

The agency gave careful consideration to the use of this term but it finally concluded that it should reject this suggestion because the term "picowave treatment" is not in common use in the industry or in the scientific community and would be neither more informative to the consumers than the label statement "treated with radiation" nor more understood by those in the food-processing industry. In addition, the microwave terminology is associated with complete cooking of the food which in no way parallels irradiation treatment of food as permitted by this final rule.

45. Several comments suggested alternative language for the wholesale label statement based on the assumption that the agency would permit reirradiation of a food provided that the total absorbed dose did not exceed the permitted amount. These comments suggested statements such as "Ionization processed with a maximum of ——— kGy" or "processed with electromagnetic energy (or picowaves) or electron beam energy (as appropriate) in the range of 0.5 MeV to 10 MeV with a dose of ——— (blank to be filled in by processor)."

Elsewhere in this document the agency has addressed the issue of reirradiation and has concluded that multiple exposure of foods to radiation is inappropriate. Therefore, there is no need to discuss these comments.

46. A few comments suggested that the wholesale label statement be replaced by a code stamp that would reflect the pertinent information about the treatment similar to that now used for the place and date of production for canned foods.

The agency has rejected this approach because the purpose of requiring a wholesale label is to alert other food processors that a food has been irradiated. The code stamp currently used in the production of canned foods is informative only to the individual canner. Different firms use different codes for their own special tracking of food lots. For a code stamp to be useful at all, there would have to be a universal code used by all manufacturers. Even this approach, however, is unsatisfactory when compared to labeling because there is a greater chance for error in interpreting a code stamp than in reading a statement that the food has been irradiated.

47. A few comments suggested that the agency permit alternative language to be substituted for any required statement to reflect more accurately the type of processing involved. In place of the phrasing "treated with ionizing radiation," the comments suggested statements such as "treated with x-rays" or "treated with gamma radiation from cobalt-60" or "treated with electron beam energy."

In the Federal Register of January 7, 1987 (52 FR 140), the agency proposed that terms such as "processed (or treated) by x-radiation" and "processed (or treated) by gamma radiation" could be substituted for "processed (or treated) by ionizing radiation" at the option of the processor, whenever the more specific treatment was applicable.

The agency concludes that the option to describe the type of radiation should still be made available to food processors. 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. Permitting these alternative labeling statements will also serve to educate the general public about the various types of treatment used by food processors.

48. Several comments recommended that FDA require a logo to represent "radiation" instead of a worded statement on the label of retail foods that have been irradiated. These comments pointed to the fact that there is a symbol used internationally to convey the fact that food has been irradiated. A comment from the U.S. Environmental Protection Agency (EPA),

although not opposed to the use of a logo to represent use of the irradiation process on food product labeling, expressed concern that the symbol that has been used internationally closely resembles EPA's official logo. EPA asserted that use of the symbol might cause consumer confusion about whether EPA had endorsed use of a product that carried such a logo.

The agency believes that the use of a logo in conjunction with a descriptive label of the process would serve to educate the general public that the logo and the label are synonymous. Thus, the agency is requiring that the label and labeling of retail packages of foods irradiated shall bear the following logo

along with the statement "treated with radiation." This logo derives from the symbol that has been used internationally to convey the fact that the food has been irradiated.

For irradiated foods not in package form, the required logo and phrase "treated with radiation" shall be displayed to the purchaser by other means as discussed elsewhere in this document. In addition, the label and labeling and invoices or bills of labeling shall bear the statement "treated with irradiation—do not irradiate again" when shipped for further processing, labeling, or packaging.

With industry uniformly using this logo in conjunction with the wording "treated with radiation" or "treated by irradiation" and an educational effort to inform consumers about the meaning of the logo, the agency has modified this rule to require 2 years after its publication only the use of the logo without the accompanying terminology. The agency will assess the need for the mandatory language to accompany the logo during this 2-year period. Any extension of the wording requirement will be established through notice and comment rulemaking.

49. Several comments argued that even if a retail label requirement were a part of the regulation that this requirement should not apply to fresh fruits and vegetables because such labeling was impracticable. Other comments simply asked how any retail label requirement would apply to fresh fruits and vegetables sold in bulk retail food stores.

The agency does not agree that retail labeling of fresh fruits and vegetables would be impractical. The final regulation as modified states that packaged fruits and vegetables include the logo and the statement "treated with radiation" on the label. For irradiated fruits and vegetables not in package form, the regulation provides three alternatives for meeting the labeling requirements. As an alternative, each item of irradiated food may be individually labeled. The agency has been informed that some companies plan to label each piece of irradiated food. 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" in order to inform the consumer that this product has been 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 and for processed foods sold in bulk without packaging.

C. Current Good Manufacturing Practice

FDA has issued general regulations regarding current good manufacturing practices (CGMP) (21 CFR Part 110) as well as specific CGMP regulations for some types of food (21 CFR Parts 113, 114, 118, 123, and 129) or food additives (21 CFR 172.5, 174.5, 182.1, 184.1). Such regulations are based on standard practices of responsible manufacturers in the industry.

The CGMP regulation for irradiated food could not be based solely on current radiation practices because of the lack of substantial experience with food irradiation. However, there has been extensive experience with other types of radiation processing (e.g., hospital supplies), and the industry has established standards in some cases. FDA considered both the experience and standard practices in the nonfood radiation processing industry and CGMP in the food industry in developing its proposed regulation for irradiated food and in evaluating comments.

In general, comments were supportive of the proposed provisions in § 179.25, including the proposed requirement for a scheduled food irradiation process, to establish a standard operating procedure specific to each food and radiation facility. Many comments supported recordkeeping requirements and emphasized the need for personnel training and FDA inspection.

50. One comment on proposed § 179.25(c) was concerned about the training that would be required of the "qualified person with expert knowledge of radiation processing" and what Federal or State agency would license or otherwise certify a radiation processing specialist who is needed to establish scheduled processes. Another comment suggested that FDA convene a panel of experts to develop a protocol for the establishment of scheduled processes for food irradiation instead of leaving it to industry experts. The comment also suggested that the Codex Standards and the Code of Practice for irradiated food be incorporated or identified as a guideline for the establishment of a scheduled process (Ref. 70). (These documents were developed by the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations, and the World Health Organization.)

The agency has no jurisdiction over the licensing or certification of radiation processing specialists. (However, see comments regarding the training of radiation safety personnel required by the Nuclear Regulatory Commission (NRC) in the section on environmental impact elsewhere in this document.) The manufacturer is responsible for choosing individuals who are qualified by appropriate scientific training and applied experience to ensure the integrity of the food irradiation process. FDA believes that there is sufficient incentive for food manufacturers to select qualified people and that FDA need not intervene. Therefore, each manufacturer is expected to select personnel having expertise and experience in the radiation processing of food and knowledge of the requirements of the particular facility. The specialist's work experience must be documented and must demonstrate training and experience in radiation processing of food. FDA believes that a background check for such personnel would be done in any case. FDA has no plans at this time to require the licensing of such individuals or to convene a panel of experts to develop a protocol for the establishment of scheduled processes. The agency agrees that the Codex Alimentarius Standard and Code of Practice is a useful guide but sees no need to require compliance with that code by regulation.

51. One comment on proposed § 179.25(d) asked if food processors who

use irradiated ingredients in their retail products are subject to the recordkeeping requirements of this regulation.

The proposed rule and this regulation limit the maintenance of records to the food irradiation processor. Therefore, a food manufacturer who uses irradiated ingredients in foods designed for retail trade is not required to maintain records related to irradiation treatment.

52. One comment on proposed § 179.25(d) requested clarification about the length of time that records must be maintained. The comment stated that some dry foods, such as spices, may have a very long shelf life that cannot always be predicted by the processor. Another comment suggested that records be maintained only 3 years.

The proposed rule would have required the records to be kept for a period that exceeds the shelf life of the irradiated food by 1 year. FDA agrees that this requirement is not clear and is amending this regulation to require that the indicated records be retained for a period of time that exceeds the shelf life of the irradiated food by 1 year, or for 3 years, whichever period is shorter.

53. One comment stated that the allowed uses of irradiation should be specified in sufficient detail so that Federal and State officials may accurately determine whether a processor is complying with the regulations. The comment suggested that FDA consider specifying sampling procedures to monitor whether a processor is complying with the regulations.

As explained in this document, irradiation of food at the permitted safe levels does not produce amounts of unique radiolytic products sufficient to be detected using conventional food sampling and analysis techniques. Nonetheless, the agency agrees with the comment that specificity of procedures is essential to ensure that radiation processing has been properly carried out. That is why this final rule lists the permitted uses of irradiation and requires that a processor have a scheduled process for each food established by a qualified person with expert knowledge of radiation processing. The scheduled process must specify a dose range that will ensure that the absorbed dose will achieve its intended technical effect on the food being irradiated. The final rule also requires that records be kept that include, among other things, evidence of compliance with the scheduled process, source calibration, and dosimetry. Moreover, these records are to be made available for inspection by authorized employees of FDA. The agency believes that this is sufficient information to determine whether processors are complying with the regulation.

54. One comment stated that no mention is made in the regulation regarding the role of State officials. The comment expressed concern about possible questions regarding State activities in the area. The comment said that State officials might be called upon to assist FDA in enforcing the final regulation and wondered whether the final regulation ought to specify whether State activities involving food irradiation processing would be preempted under the regulation.

The act contains no specific provision preempting the field of food irradiation. The test of whether a State activity is preempted by Federal law and regulations is whether the State activity conflicts with and stands as an obstacle to the Federal program. The comment appeared to be concerned about whether State inspections or other actions in support of this final regulation would be preempted by this regulation. FDA notes that State officials routinely assist FDA in inspecting certain facilities that are within their State in order to conserve scarce agency resources. The agency has, for many years, worked closely with the States through cooperative work-sharing agreements affecting compliance with the act and its implementing regulations. These cooperative efforts would further the goal of this regulation and would not be precluded under any preemption doctrine.

55. Some comments stated that a regulation requiring access only to records is not adequate to ensure compliance, and that FDA should also propose strict monitoring or some degree of official inspection.

The agency has authority to conduct plant inspections for all food-processing plants. FDA did not intend to imply that compliance would be determined solely by inspection of records. FDA officials will inspect food irradiation plants and will copy and review required records to assure that the processor is complying with these regulations. The agency would like to clarify that it considers inspection of records to include copying of the records for further review, and is, therefore, adding the words "and copy" after "inspection" in new § 179.25(e) for the same reasons stated in the proposal for records inspection requirements (48 FR at 5719) based on sections 409, 703, and 704 of the act. Thus, if a food manufacturer chooses to engage in radiation processing of food, FDA will consider that processor to have waived any objections to the agency's requirement of inspecting and copying pertinent records with respect to irradiated foods.

56. One comment stated that testing of food irradiation dosage is limited by the accuracy of the testing dosimetry. The comment stated that the regulation must provide methods for determining the absorbed dose which can be directly related to standards of radiation maintained by the National Bureau of Standards.

The agency agrees that the accuracy of the testing dosimetry is important. Assuring accurate dosimetry is a part of developing a scheduled process. Nevertheless, optimum procedures for dosimetry may change, and FDA does not intend to limit dosimetry to any one specific system at this time. FDA would consider irradiation of food without adequate dosimetry to be a violation of the current good manufacturing practice regulations.

57. A few comments requested that the regulation permit multiple irradiations of food provided that the maximum dose limitation prescribed by regulation is not exceeded. The comments argued that there are conditions where a second radiation treatment would produce a useful effect without exceeding the maximum dose. One comment stated that the Codex Alimentarius standard for irradiated foods does permit reirradiation of foods under limited circumstances.

The agency disagrees that the regulation should permit the multiple irradiation of foods for the following reasons:

(1) An irradiated food that is properly packaged and stored should not require further irradiation to be marketable. Irradiation processing of food is not to be used as a substitute for good food sanitation practices.

(2) Where a food is irradiated more than once, the cumulative radiation dose cannot exceed the maximum allowable dose prescribed in the regulation. The determination of whether those foods that are irradiated more than once are in compliance with the regulation would be difficult and impractical, if not impossible. Inspection of irradiation records alone to determine compliance would be inadequate. Records maintained by different irradiation facilities with respect to the reirradiated food would not be available for inspection simultaneously. Moreover, if a food were irradiated in a foreign country and subsequently irradiated in the United States, the absence of records from the foreign radiation facility would make a determination of compliance with the regulation impossible.

(3) FDA is aware of the Codex Alimentarius standard concerning reirradiation of foods (Ref. 70). The Codex Alimentarius standard does not permit reirradiation of foods, except for foods with low moisture content (cereals, pulses, dehydrated foods, and other such commodities), irradiated for the purpose of controlling insect reinfestation. This same standard, however, states that a food is not considered to have been reirradiated when: (1) The food prepared from materials, which have been irradiated at low dose levels, is irradiated for another technological purpose; (ii) the food, containing less than 5 percent of an irradiated ingredient, is irradiated; or (iii) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one installment as part of procesing for a specific technological purpose. In accordance with 21 CFR 130.6, FDA will review all food standards adopted by the Codex Alimentarius Commission. The agency is not required, however, to accept these standards.

Although the agency may, on its own initiative, propose adoption of a Codex standard under section 401 of the act (21 U.S.C. 341), any interested person may petition the agency to adopt a Codex standard (21 CFR 130.6). Because the agency has not proposed adoption of the Codex standard regarding reirradiation of foods as part of this rulemaking, this issue requires no further discussion at this time.

(4) The agency acknowledges that there could be certain circumstances where a useful effect could be produced by reirradiating a food without exceeding the maximum dose limitation prescribed by the regulation. However, as discussed earlier in this response, the agency believes that efforts to monitor compliance with this regulation through recordkeeping and records inspection would be difficult and impractical, and may even be impossible in certain instances. A further complication that would arise should reirradiation of foods be permitted involves the difficulty of complying with the labeling requirements prescribed by the regulation. Complex labeling at the wholesale level would be needed to ensure that the maximum cumulative dose absorbed by the food does not exceed the maximum dose limitation prescribed by the regulation. Wholesale labeling would also have to convey to what extent a previously irradiated food was treated. Furthermore, such cumulative doses would have to be the minimal radiation dose reasonably required to accomplish the intended technical effects. This minimal radiation dose would be very difficult to determine if it is administered in multiple doses. These complex issues would require careful consideration by the agency during a separate evaluation. For all of these reasons, the agency has concluded that reirradiation of food should not be permitted under this regulation.

58. Some comments questioned the need for a 5 million electron volt limit for x-ray sources and stated that this energy limit should be increased to 10 million electron volts.

The 5 million electron volt limitation for x-ray sources was based on data in an earlier petition and is consistent with recommendations of the Codex Alimentarius Commission. FDA has no data demonstrating the safety of sources operating at higher energy levels; accordingly, this regulation approves the use of x-ray sources of no more than 5 million electron volts. The agency will consider changing the limitation if data supporting the safe use of x-rays produced by machines using energy sources greater than 5 million electron volts are submited in a food additive petition.

D. Other Technical Effects

59. Several comments were opposed to food irradiation because it can theoretically affect the metabolic processes of fresh foods, and thereby conceivably make them less resistant to spoilage by various fungal diseases.

The agency recognizes that irradiation affects the metabolic processes of fresh foods and may sometimes make them less resistant to spoilage. Irradiation, like other processes, will not solve all food-preservation problems and will sometimes be impractical. Food processors would probably not irradiate food if irradiation causes the food to spoil more quickly or to become less marketable. In such cases, irradiating food would be contrary to the processor's self-interest. Because the practicality of using food irradiation makes this process somewhat self-limiting, the agency concludes that it need not restrict the irradiation of fresh foods merely because some foods may be unsuited to such processing.

60. Many comments requested that FDA take a more general approach to permit irradiation up to a dose of 1 kGy on any food for any purpose consistent with current good manufacturing practice. One comment stated that the rule should be extended beyond fruits and vegetables to mushrooms and pork. Several comments asked that the safe dose be raised to 1.5 kGy (150 krad). The comments stated that 0.75 kGy (75 krad) is necessary for maximum shelf life extension of papaya, and the 1.5 kGy safe dose would allow for some latitude in designing a commercial food irradiator. One comment stated that the term "insect control" may be too restrictive and suggested "pest control." Several comments stated that a maximum dose of 1 kGy is effective for trichinae control and for microbial control in some foods.

The agency intended the term "fresh fruits and vegetables" to include mushrooms, which are fruiting bodies of fungi. The agency now believes that the term "fresh foods" may more adequately describe foods such as fruits, vegetables, and mushrooms that are capable of additional growth and maturation but that may be treated with ionizing radiation to inhibit those processes. FDA is revising the regulation accordingly. In addition, the agency agrees that the term "insect control" may be too restrictive. Therefore, the agency is substituting the term "arthropod pests" to include insects, spiders, and mites, but to exclude pests such as bacteria, molds, mice, and rats.

Although the agency believes that the safety of food irradiation below 1 kGy (100 krad) has been established, the agency proposed to limit the use of food irradiation according to intended technical effect rather than simply by dose. This was done both to avoid indiscriminate use of irradiation and to aid enforcement of dose limits because there would be no reason to exceed the permitted dose for the allowed technical effects. For example, overtreatment of fruits and vegetables may adversely affect their marketability. Thus, exceeding the permitted dose would result in a substandard product. In effect, compliance occurs due to a self-limiting factor.

In the specific case of papaya, the agency believes that an adequate commercial radiation facility can be designed for papaya with the current limitation. Alternatively, the agency will review a petition to increase the maximum permitted dose for fresh foods.

The agency is aware that the permitted dose may also be somewhat effective for other uses, such as decreasing the microbial burden in meat, fish, and poultry. FDA did not propose these uses, however, because irradiating at such low doses would not be sufficiently effective for microbial control to be self-limiting. The agency stated in the proposed rule that it would consider other uses below 1 kGy (100 krad) if a petition supported by evidence that a specific technical effect can be

accomplished below 1 kGy (100 krad) and if an appropriate food additive regulation can be promulgated and can be enforced. The agency has received petitions for the use of irradiation to control trichinae in pork at doses below 1 kGy 100 krad). As discussed earlier in this preamble, the agency issued a final rule on July 22, 1983, in response to one petition to control *Trichinella spiralis* in pork (50 FR 29658). In this document, the agency is deleting § 179.22 and is incorporating that authorization for the irradiation of pork in new § 179.26(b).

61. One comment stated that FDA's proposed rule would have relatively little impact on solving the overall problem of food spoilage and contended that FDA is apparently seeking to avoid, delay, or otherwise shelve indefinitely the approval of irradiation at higher dose levels. The comment stated there is no reason for FDA's reluctance to proceed on its own initiative to approve food irradiation at doses above 1 kGy, including radiation sterilization of chicken. Other comments stated that FDA should permit doses up to 10 kGy based on the Codex Alimentarius standard.

FDA's traditional approach to issuing a food additive regulation has been to respond to a properly documented petition. FDA initiated this rulemaking to permit food irradiation because it believed that an agency-initiated rulemaking would be more efficient for those uses where the agency needs no further safety data.

Two considerations prevent the agency, at this time, from proposing a general regulation allowing higher doses. First, at higher doses, irradiation can significantly retard microbial spoilage without killing all spores of *C. botulinum*. Under some conditions, *C. botulium* can grow and produce a toxin that consotutes a health hazard. Based on current information, the agency is unable to prescribe safe conditions of irradiation at higher doses for foods that would ensure *C. botulinum* organisms would not develop.

Second, at the doses permitted in this regulation, the total amount of radiolytic products consumed is too small to be of concern, either because of low doses or because foods so treated are a minor part of the diet. Further, safety information from animal feeding studies is unnecessary under these circumstances. The proposal stated that FDA is reviewing a number of studies to determine whether foods that are irradiated at doses above 1 kGy (100 krad) can be considered safe without additional toxicological studies. As stated elsewhere in this document, the agency has reviewed these studies and found that five were acceptable by current standards. This data base is inadequate to support a broad decision that all foods may be irradiated safely at higher doses up to 10 kGy (1 Mrad).

Therefore, FDA does not intend to initiate further rulemaking on food irradiation based on the information before it at this time. The agency will, of course, continue to evaluate and respond on a case-by-case basis to all food additive petitions involving irradiation.

62. Several comments discussed using irradiation to control microbial contamination of animal feeds. One comment stated that the agency should consider the use of irradiation to treat all animal feeds up to a maximum dose level of 25 kGy (2.5 Mrad).

The agency agrees that irradiation of animal feeds to control microbial contamination could be addressed, but not necessarily as part of this rulemaking. Ralston Purina Co. filed a food additive petition (FAP 2198) (December 18, 1984; 49 FR 49181) proposing that the regulations be amended to provide for microbial disinfection of laboratory diets for rats, mice, and hamsters by radiation treatment. The agency responded to this petition in the Federal Register of February 19, 1986 (51 FR 5992). Any interested person able to document the safe use of a source of radiation to treat animal feeds may submit an animal food additive petition for that use under the provisions of 21 CFR Part 571.

63. One comment stated that the agency should permit the use of radiation to sterilize meals to provide a more nutritious and palatable diet for persons who require sterile meals.

The agency is considering a separate rulemaking to permit the investigational use of unapproved food additives under section 409(i) of the act (21 U.S.C. 348(i)). That issue is not relevant to the uses of food irradiation permitted under this regulation.

64. Several comments stated that there were other alternatives to irradiation for insect control or for growth and maturation inhibition of fresh fruits and vegetables and that, therefore, there was no need to permit food irradiation.

The agency agrees that there are other methods both for insect control and to inhibit the growth and maturation of fresh fruits and vegetables. However, the existence of such methods is not a reason to prohibit equally safe alternatives, nor does the act authorize FDA to arbitrarily limit the safe alternatives that are to be allowed. The agency believes that the marketplace should determine which alternative treatment method is used when safety is not an issue.

E. Packaging

65. One comment stated that FDA should consider the possible migration of toxic substances from packaging materials to food during irradiation. Several comments noted that the proposed rule does not discuss packaging materials and that this omission may create confusion with respect to § 179.45. In addition, one comment asked specifically whether the irradiation of bulk packaging materials such as fiber drums and burlap bags is permitted even though they are not listed in § 179.45. The comment questioned the need for § 179.45 and suggested, as an alternative, granting approval for irradiation of all substances that are currently generally recognized as safe as packaging materials.

FDA points out that all packaging materials or components of packaging material that may reasonably be expected to migrate to food must comply with appropriate regulations authorizing their use. Components of packaging materials that have been irradiated may migrate to food to a different degree than components of an unirradiated material.

There are two aspects to this problem: (1) A packaging material that is irradiated before food contact may degrade or undergo crosslinking or some other change so that it is significantly different from the nonirradiated material and (2) packaging material irradiated while in direct food contact may produce low molecular weight materials that might migrate into the food.

In the first case, the irradiated material may be tested to see whether it is suitable for use in contact with food and complies with appropriate regulations. If the irradiated material is still suitable for use and complies with the applicable regulations, no additional regulations are required. If the irradiated material no longer complies with applicable regulations, interested persons may submit a food additive petition to amend the regulations accordingly.

In the second case, volatile materials migrating into prepackaged foods during irradiation would not have been considered in evaluating whether the packaging material was safe for its intended use, unless the packaging material had been specifically authorized under § 179.45. Section 179.45 lists packaging materials that may be formed into containers for holding or packaging food intended to be irradiated

and which may be subjected to incidental irradiation during the radiation treatment of prepackaged foods. This regulation was issued in response to petitions for packaging materials used with food during irradiation in anticipation of expanded uses of food irradiation in the 1960's. Therefore, the agency disagrees with the comment that § 179.45 is unnecessary.

Section 179.45, however, does not list packaging materials that are generally recognized as safe (e.g., glass, wood, natural fibers) but which may exhibit different characteristics of migration to food during irradiation. FDA knows of no information on such materials during irradiation by which they could be generally recognized as safe. Therefore, FDA does not consider such materials to be generally recognized as safe when used in packaging that is irradiated in contact with food. The agency invites petitions to amend § 179.45 to include generally recognized as safe packaging materials and other packaging materials not currently in § 179.45.

The agency agrees that the failure to address packaging in the proposal may cause confusion. Because of the possible confusion, FDA is adding a new paragraph in § 179.26 clarifying the intended requirement that packaging materials containing food during irradiation must comply with § 179.45.

F. Public Education

66. Many comments stated that a need exists for a public education campaign supported by the government and industry.

The agency agrees that there is a need for public education in this area. However, the agency is responsible for ensuring that food additives including a source of radiation are safe; FDA has no proper role as a promoter of a specific food additive or food process. The agency believes that the primary responsibility for such educational activities remains with industry in this instance.

G. Impact Analyses

The agency stated in the proposed rule that existing safeguards in regulations issued by the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), the Department of Transportation (DOT), and FDA are adequate to ensure that there will be no adverse environmental effect. However, many comments expressed concerns about the environmental impact of this regulation. These comments can be separated into three categories: (1) Radiation safety within the facility (worker safety), (2) waste storage and disposal, and (3) transportation. FDA requested a response to these comments from OSHA (Ref. 71), NRC (Ref. 72), and DOT (Ref. 73) and has summarized their responses below.

67. Several comments were concerned with worker exposure and with plant safety and claimed that current safety standards are inadequate to protect workers employed in industries handling radioactive materials.

A facility using radioactive material must first obtain a license from NRC or the corresponding agency in an agreement State. NRC has informed FDA that in order for a firm to be licensed to possess and use radioactive material in an irradiator, the firm must file an application with NRC or the corresponding State agency. The information that needs to be submitted includes the training and experience of individuals responsible for the radiation safety programs, the training provided to persons who will work under the supervision of the responsible individuals, a description of the facility, the safety systems designed to protect personnel from exposure to radiation, and the radiation protection program.

NRC states that the regulatory "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators" (Ref. 74) provides guidance to potential applicants about specific details needed in an application for possession and use of radioactive material in an irradiator. The NRC staff reviews the application to determine that (1) the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life and property, (2) the applicant is qualified by training and experience to use the radioactive material for the purpose requested and in such a manner as to protect health and minimize danger to life and property, and (3) the program described will result in compliance with NRC's regulatory requirements. If the information provided in an application is satisfactory, a license is issued. After issuance, NRC conducts periodic inspections of irradiator facilities. In 1978 and 1979, NRC collected exposure data from all licensees. The average annual measurable dose for persons engaged in irradiation operations was 160 millirems. (The maximum permissible ionizing radiation dose for workers is 5,000 millirems per year.)

68. One comment stated that OSHA's ionizing radiation standard (29 CFR 1910.96) would apply to worker exposures from machine-produced radiations, but questioned the organization's ability to ensure worker safety.

In response to this comment, OSHA confirmed that its current ionizing radiation standard (29 CFR 1910.96) would apply to worker exposures to radiation from machine-produced sources. As in the past, OSHA will concentrate its inspectional resources on high priority problems, and will consider additional action should information develop indicating a need for concern.

69. Many comments were concerned about the safety of transporting radioactive materials, in general, and also argued that implementation of this regulation would lead to increased amounts of radioactive materials being transported.

Both DOT and NRC have responded to this comment. They stated that the transportation of radioactive materials is an activity which is highly regulated by both the Federal and State governments. Both DOT and NRC have regulatory requirements that govern all aspects of transportation in detail, from quality assurance in packaging to requirements for posting information that is clearly visible on transporting vehicles.

The overall safety of transporting radioactive materials was evaluated in the NRC report entitled "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes" (NUREG-0170) (Ref. 75). The report concluded that the total risk from all transportation of such materials was acceptably low. NRC has concluded, after review of the subject, that the regulations are adequate to protect the public against unreasonable risks from the transport of radioactive materials (46 FR 21619; April 13, 1981). NRC believes such shipments can be made safely because licensees shipping radioactive material for use in food irradiators are required to comply with an NRC regulatory program.

Food irradiation sources are held in the form of welded, sealed sources and are transported in accident-resistant packaging. There has never been a release of radioactive materials from one of these packages in the United States as a result of a transportation accident, even when transporting powders, liquids, or gases. The transportation of sealed sources would make a release even more unlikely.

70. One comment stated that DOT, NRC, and the States are ineffective in their regulation of transportation of radioactive materials.

DOT disagreed and stated in a letter to FDA that the approach being used by NRC, DOT, and the States has been effective in ensuring safety.

71. One comment stated that the absence of effective regulations for transporting radioactive materials has prompted over 200 local communities to impose bans or restrictions on nuclear cargo transportation in defiance of Federal preemption.

DOT advised FDA that this is a misleading statement. DOT has no evidence that the transportation of radioactive materials has caused any safety problem. DOT pointed out that there may be a myriad of reasons behind these local restrictions, many of which may be unrelated to safety. Finally, the existence of local restrictions against the transport of radioactive material provides no evidence that there is or has been a safety problem associated with such transportation.

72. One comment stated that the history of monitoring transportation of radioactive materials leaves much to be desired. The comment cited incidents reported over the past 2 years where (1) sources were simply "lost" or were found by children in public, unrestricted areas; (2) sources were accidentally mixed with scrap metal; or (3) offsite contamination from radiation byproduct facilities resulted in widespread contamination. The comment further questioned what would happen when millions of curies are added to the commercial sector, if the Federal government cannot keep track of the approximately 17,000 sources in the United States.

DOT advised FDA that the references made by the comment to lost sources are misleading. The incidents referred to did not involve sources as large as those to be used in a food irradiator. Sources that have been lost in transit in the United States have been those of very low activity or empty packages that pose relatively small risks. High activity sources such as those used for food irradiation are transported in large, heavy packages which are not likely to be easily lost. Additionally, DOT's regulations require that the shipper of such packages notify the consignee when a shipment is made so that the consignee expects it and can take prompt action if it is not delivered on time. The comment about radioactive material being mixed with scrap metal refers to an incident in which a radioactive source was incorporated into steel made from scrap metal. This incident involved international licensing authorities and had nothing to do with domestic transport.

The agency has determined that the existing controls over the transportation of radioactive materials are adequate to ensure safety even when the number of radiation sources increases, as might be expected as a result of this rule.

73. Many comments expressed concern that an increased use of radioactive materials will lead to a corresponding increase in problems regarding proper disposal of radioactive wastes and possible environmental contamination.

Under NRC's regulations, sealed sources used in an irradiator may be disposed of by transfer to an authorized recipient as specified in 10 CFR 20.301(a). An authorized recipient could be the original supplier of the sealed sources, another licensee which is authorized to possess the sealed sources, or a facility licensed to receive and dispose of radioactive wastes.

In practice, a cobalt-60 sealed source is usually returned to the original supplier at the end of its useful life. Disposal of the sealed sources could be accomplished by transfer to one of the existing facilities authorized to dispose of radioactive waste materials. In the United States, these facilities are located in the States of South Carolina, Nevada and Washington. With respect to the cesium-137 capsules which the Department of Energy (DOE) has available for use in irradiators, DOE will lease the capsules to licensees and the capsules will be returned to DOE at the end of their useful life.

The agency believes that these measures are adequate to safeguard against possible environmental contamination.

74. Many comments were concerned that food irradiation might cause the formation of mutant pathogens. One comment stated that an environmental impact statement must be filed for this reason by the agency before further action is taken.

The agency considered the potential environmental impact of permitting food irradiation and concluded that an environmental impact statement was not required, and submitted this finding of no significant impact and environmental assessment to the docket for public review, as noted in the proposal. No new information or comments have been received that would alter the agency's previous determination. A response to the comment that mutant pathogens may result during food irradiation has been provided earlier in this document.

75. Various comments on the economic impact of this process stated that this process would provide consumers with a greater variety and quantity of foods than that now available because of quarantine restrictions or limited shelf life. Other comments stated that the process is expensive and thus would increase the price of food. Comments from industry stated that the costs involved in commissioning a facility would require a broader range of uses to make the operation financially viable.

The agency believes that the marketplace will determine whether irradiation of food is economically feasible. No information was provided to suggest that issuance of this final rule would pose an unacceptable economic burden on society.

III. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 19, 1986 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following sources referred to in this document are listed below. Documents with an asterisk (*) have been placed on display in the Dockets Management Branch (address above), and may be seen between 9 a.m. and 4 p.m., Monday through Friday. All the references not on display are available as published articles, reports, and books.

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V. Agency Action

FDA has evaluated over 5,000 comments as well as information already in FDA's files and concludes that the proposed use of ionizing radiation is safe and that the regulations should be amended as set forth below.

The agency assessed the impact of the proposed rule on current and future uses of irradiation technology (February 14, 1984; 49 FR 5714). This assessment demonstrated that the proposed rule was not a major rule as defined by Executive Order 12291.

Further, it was determined that the rule would not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act. In order to accurately reflect changes in this final rule made in response to comments, FDA has prepared a revised threshold assessment of the economic effects of this rule. The findings of this assessment do not alter the agency's previous assessment. Therefore, the agency hereby finds that this is not a major rule as defined by that Order and certifies in accordance with section 605(b) of the Regulatory Flexibility Act that the rule will not have a significant economic impact on a substantial number of small entities.

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (February 14, 1984; 49 FR 5714). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

Section 179.25(e) of this final rule contains a collection of information requirement. FDA submitted a copy of the proposed rule containing the same requirement to the Office of Management and Budget (OMB). This collection of information requirement was approved for use through March 31, 1987 (OMB Control No. 0910–0186).

List of Subjects in 21 CFR Part 179

Food additives, Food packaging, Irradiation of foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF FOOD

1. The authority citation for 21 CFR Part 179 is revised to read as set forth below and the authority citations under 21 CFR 179.21 and 179.45 are removed.

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10; §§ 179.25 and 179.26 also are issued under secs. 402, 403, 703, 704, 52 Stat. 1046–1048 as amended, 1057, 67 Stat. 477 as amended (21 U.S.C. 342, 343, 373, 374); 21 CFR 5.10, 5.11.

§ 179.22 [Removed]

2. By removing § 179.22 *Gamma radiation for the treatment of food.*

§ 179.24 [Removed]

3. By removing § 179.24 *Low-dose electron beam radiation for the treatment of food.*

4. By adding new § 179.25, to read as follows:

§ 179.25 General provisions for food irradiation.

For the purposes of § 179.26, current good manufacturing practice is defined to include the following restrictions:

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of Part 110 of this chapter and other applicable regulations.

(b) Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use.

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods shall comply with § 179.45.

(d) Radiation treatment of food shall conform to a scheduled process. A scheduled process for food irradiation is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility. A food irradiation processor shall operate with a scheduled process established by qualified persons having expert knowledge in radiation processing requirements of food and specific for that food and for that irradiation processor's treatment facility.

(e) A food irradiation processor shall maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter, and shall make these records available for inspection and copy by authorized employees of the Food and Drug Administration. Such records shall include the food treatment, lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

[Collection of information requirements approved by the Office of Management and Budget under control number 0910-0186]

5. By adding new § 179.26, to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies not to exceed 10 million electron volts.

(3) X-rays generated from machine sources at energies not to exceed 5 million electron volts.

(b) *Limitations.*

Use	Limitations
For control of *Trichinella spiralis* in pork carcasses or fresh, non-heat-processed cuts of pork carcasses.	Minimum dose 0.3 kGy (30 krad); Maximum dose not to exceed 1 kGy (100 krad).
For growth and maturation inhibition of fresh foods.	Not to exceed 1 kGy (100 krad).
For disinfestation of arthropod pests in food.	Do.
For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes).	Not to exceed 10 kGy (1 Mrad).
For microbial disinfection of the following dry or dehydrated aromatic vegetable substances: culinary herbs, seeds, spices, teas, vegetable seasonings, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives.	Not to exceed : .Gy (3 Mrad).
The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends.	

(c) *Labeling.* (1) The label and labeling of retail packages of foods irradiated in conformance with paragraph (b) of this section shall bear the following logo

along with either the statement "Treated with radiation" or the statement "Treated by irradiation" in addition to information required by other regulations. The logo shall be placed prominently and conspicuously in conjunction with the required statement.

(2) For irradiated foods not in package form, the required logo and phrase "Treated with radiation" or "Treated by irradiation" shall be displayed to the purchaser with either (i) the labeling of the bulk container plainly in view or (ii) a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. As an alternative, each item of food may be individually labeled. In either case, the information must be prominently and conspicuously displayed to purchasers. The labeling requirement applies only to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated.

(3) For a food, any portion of which is irradiated in conformance with paragraph (b) of this section, the label and labeling and invoices or bills of lading shall bear either the statement "Treated with radiation—do not irradiate again" or the statement "Treated by irradiation—do not irradiate again" when shipped to a food manufacturer or processor for further processing, labeling, or packing.

(4) The wording requirements of paragraphs (c)(1) and (2) of this section pertaining to the label and labeling of retail packages of food shall expire April 18, 1988, unless extended by the Food and Drug Administration by publication for notice and comment in the Federal Register.

Frank E. Young,

Commissioner of Food and Drugs.

Dated: March 29, 1986.

Otis R. Bowen,

Secretary of Health and Human Services.

[FR Doc. 86-8684 Filed 4-15-86; 11:05 am]

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ALASKA STATE LEGISLATURE
HOUSE OF REPRESENTATIVES
RESEARCH AGENCY

P.O. Box Y, State Capitol
Juneau, Alaska 99811-3100
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May 6, 1988

MEMORANDUM

TO: Representative Randy Phillips

ATTN: Janet Seitz

FROM: Patricia Brawley
Legislative Analyst

RE: **Food Irradiation by Machine-Generated Electron Beams**
Research Request 88.251

You requested information about the machine-generated source of radiation recently recommended by the University of Alaska's Institute of Northern Engineering Food Irradiation Project. You specifically wished to know about the process of food irradiation by electron beams, and the type of fuel used in this process.

High energy electron beam machines are capable of producing, as sources of radiation, accelerated electrons (high energy electron beams) and X-rays. Like X-ray machines in hospitals and dental offices, they are powered by electricity. They contain no radioactive isotopes or materials, so the machines are harmless when the electricity is disconnected. Potential environmental and health risks involved in transportation, storage, and handling of radioactive isotopes (cesium 137 and cobalt 60) are thus eliminated. Problems involving facility maintenance, as well as possible damage from earthquakes, tsunamis, or other disasters are also eliminated. During use, as with X-ray machines, operators must be biologically shielded from the beams produced.

Unlike radioactive isotope sources, which constantly emit gamma rays, machine-generated sources work by a principle of kinetic energy: when objects are not in motion, energy is potential; when in motion, energy is kinetic. According to Dr. John Zarling, Director of the Institute of Northern Engineering and principal investigator of the food irradiation project,

> High energy electrons are produced when electrons emitted from a filament or cathode are accelerated by an electric field in a vacuum tube. This beam of electrons then passes through an alternating magnetic field where it is 'scanned' so it can emerge through a thin metallic window in a fan-shaped configuration.[1]

X-rays are created when high energy electrons hit a metal plate and are accelerated to a very high velocity. Electron beams do not penetrate as deeply as do X-rays, but they are more cost effective to use. High energy electron beams, like X-rays, can be directed or aimed, and thus are both more controllable and more efficient than gamma rays, which are emitted constantly and in all directions.

Hitting lead causes electrons to slow sufficiently for kinetic energy to be lost. Thus, according to Dr. Zarling, high energy electron beam irradiation facilities would require maze-like construction with thick walls of concrete and lead to contain and slow the beams until they return to a harmless state.

All sources recommended for food irradiation (accelerated electrons, X-rays, and gamma rays) produce similar results in foods. Ostensibly, the electron beam machine <u>as a process</u> is far less risky than other potential processes. Questions about the safety of the <u>product</u>--a separate but equally important issue--remain unchanged.

I hope this information is useful to you. If you have further questions, please call.

---

[1]Quoted by Dr. Zarling from Morrison and Roberts, "Food Irradiation: New Perspectives on a Controversial Technology," U.S. Department of Agriculture, December 1985.

Patrick A. Lynch, M.D.
Radiologist
209 Moller Avenue
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June 2, 1988

Representative John Sund
Alaska State Legislature
House of Representatives
P. O. Box Y, State Capitol
Juneau, AK 99811-3100

Dear Representative Sund:

I have come across a copy of a memorandum directed to your attention for the attention of Peggy Sepulveda from Patricia Brawley, Legislative Analyst re the Food & Drug Administration--Objectivity and Reliability Relating to Food Irradiation, your Research Request 88.202.

In reading the response I have the very definite feeling that the analyst sensed a feeling of opposition to food irradiation for the analysis seems quite slanted.

I would, however, point out to you the erroneous conclusion reached in the last paragraph wherein the FDA is accused as being an intermediary for the Department of Energy in a coordinated effort to shift the responsibility for byproducts of nuclear weapon production elsewhere. May I strongly point out to you that this specifically refers to Radioactive Cesium 137 which has been encapsulated and stored at Hanford for many years without incident. Contrary to the opponents of food irradiation Radioactive Cesium 137 is the most ideal isotope for use in irradiation of food no matter what its origin may have been. It has a half-life of 30 years far exceeding that of man made radioactive cobalt. It has an ideal energy of 0.67 MEV thus requiring less protection and source shielding. It has not proven to be any more difficult to handle than any other isotope having been encapsulated safely for over 20 years and used in the Sandia Project.

I would hope that before any final conclusions are reached in your committee that the studies on the safety on radioactive isotopes,

specifically, radioactive Cesium 137 conducted by Dr. Garth Tingey, Batelle Northwest Laboratories of Richland, Washington, under commission from the United States government be available for part of your deliberations so that they may be conducted on the basis of fact and not on wide spread untruths as are promulgated in the last sentence of your analysts report.

Very Truly Yours,

Patrick A. Lynch, M.D.

Patrick A. Lynch, M.D.
Diplomate of the American
Board of Radiology

cc: Patricia Brawley
Peggy Sepulveda

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TESTIMONY BEFORE THE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
OF THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE
BY
RICHARD PICCIONI, PH.D.
SENIOR STAFF SCIENTIST
ACCORD RESEARCH AND EDUCATIONAL ASSOCIATES
JUNE 19, 1987

I am Dr. Richard Piccioni, Senior Staff Scientist with Accord Research and Educational Associates, a not-for-profit public health research group based in New York City. I hold a doctorate in biophysics from the Rockefeller University, conducted three years of postdoctoral research at the Rockefeller supported by grants from the National Science Foundation and the National Institutes of Health, and was an assistant professor of biological science at the City University of New York, where my research was funded by the US Department of Agriculture and the MacArthur Foundation.

Over the past twenty months a team of biologists, chemists, physicians, and statisticians in our organization have carried

out an in-depth examination of the technical basis of the Food and Drug Administration's recent approvals of food irradiation processing. We feel that there is no assurance in the scientific literature or the arguments of the FDA that the widespread irradiation of food will not be a significant, if silent, threat to the public health. In summary, we feel the FDA has adopted scientifically indefensible criteria for assessing, and in their view, demonstrating, the safety of irradiated foods.

The unique nature of food irradiation processing

Treatment of food with ionizing radiation presents issues of food safety qualitatively unlike those posed by any other food processing method or food additive. The large amount of energy contained in ionizing radiation provides the potential for exceedingly complex chemical transformation of food components, including the production of mutagenic or carcinogenic substances which were not present, or were present in far smaller amounts, before irradiation. This potential far exceeds that of ordinary heat processing, microwave radiation, etc., because the energy contained in each "quantum" of gamma radiation is so great. At the same time, because the production of these "radiolytic

products" takes place within the food itself, it is impossible to design a toxicological test in which animals are exposed to exaggerated doses of these products, the chemical identity of which remains largely unknown. Thus toxicologists are limited to biological testing which is thousands of times less sensitive than the testing typically required or other chemical additives or pesticide residues.

It should be clearly understood that without toxicological testing at exaggerated doses, the carcinogenic risk to large human populations ingesting any additive or residue is impossible to assess. Exposure of test animals to exaggerated doses is the most basic tool in use in estimating carcinogenic risk. In the case of food irradiation, this tool is simply not available.

At the same time, evidence from other types of experiments provides a strong indication that mutagens and/or carcinogens are indeed present in irradiated foods. What such experiments are unable to provide, however, is a quantitative estimate of the risk. In the absence of such a estimate, it is completely irresponsible to proceed with the sale and distribution of irradiated foods. Consequently, recent approvals by the FDA for food irradiation processing should be immediately rescinded.

Basis of FDA's approvals

To understand how this has come to pass, we must briefly review some recent history: In 1979, after years of controversy and false starts, radiation food processing was re-evaluated by a specially appointed FDA committee, the BFIFC (Bureau of Foods Irradiated Foods Committee). They acknowledged that feeding whole, irradiated foods to test animals, even over long periods of time, was completely inadequate to assess the carcinogenic potential of the radiolytic products present in those foods. As an alternative to direct biological testing, they proposed acceptance of a theoretical calculation of the maximum concentration of radiolytic products present in irradiated food and made the extraordinary leap of faith that parts-per-million residues of unknown substances pose no risk when ingested by millions of people over their entire lives.

Subsequently, an FDA task force reiterated the BFIFC recommendations, and reported the results of an elaborate "review" of the available literature on the toxicological testing of irradiated foods, testing which they, as well as the BFIFC, agreed was inherently incapable of providing definitive evidence of the safety of irradiated foods. The five studies which have been mentioned by others at this hearing provided, according to the FDA itself, only the assurance that irradiated food is not wildly mutagenic and/or carcinogenic. The task

force therefore justified its conditional approval of irradiation of fruits and vegetables with up to 100 kilorad, and spices with up to 3 million rad, on the same theoretical basis as proposed by BFIFC.

Positive evidence of carcinogenic risk

Proponents of food irradiation commonly claim there are no studies in the scientific literature showing mutagenic or carcinogenic activity in irradiated foods or food components. In fact, as our own literature survey has shown (Table I) dozens of such studies exist, observed in a variety of biological systems , published by a variety of authors in a variety of peer-reviewed scientific journals over a period of twenty years. Proponents of food irradiation commonly claim that the chemical changes occurring in irradiated foods are thoroughly understood, and that there have been no studies indicating the formation of known mutagens or carcinogens. In fact, a substantial number of studies can be found in the open scientific literature indicating the presence of known mutagens, carcinogens, or cytotoxic substances in food or food components which have been irradiated (Table 2). Furthermore, the radiation chemistry of foods is far from fully understood, as evidenced by a steady appearance in the literature of studies on new radiolytic products found in various irradiated foods (e.g., Simic and Jovanovic (1986), Akhlaq et al. (1987)). Many of

these radiolytic products have not been individually tested for mutagencity or carcinogenicity.

In short, the available scientific literature provides evidence to make a strong presumption of carcinogenicty in some if not all irradiated foods. The question is one of quantifying the risk.

Pesticide replacement

In the absence of a quantitative estimate of the carcinogenic risk posed by the consumption of irradiated foods, there is no basis to the further claim that food irradiation could replace carcinogenic pesticides with an improvement in the overall quality of the food supply. Recently, the National Academy of Sciences (1987) identified 23 pesticides which are responsible for the vast majority of the total carcinogenic risk posed by the presence of pesticide residues in the US food supply. Food irradiation would make essentially no contribution to the elimination of these pesticides since of the 23, several are herbicides or insecticides applied in the field to prevent pre-harvest losses (Chemical and Pharmaceutical Press, 1987), and the remainder are fungicides, whose replacement by irradiation is a highly dubious proposition (Sommer, 1966 and personal communication). In fact irradiation of fruits and vegetables may well increase, rather than decrease, the

requirement for post-harvest application of fungicides because irradiated products are more susceptible to infection by molds and fungi (Sommer, op. cit., and Niemand et al., 1985).

Radiation treatment of Salmonella-contaminated poultry

On the question of the use of ionizing radiation to inactivate Salmonella in poultry, it is important to understand two points::

1. Doses required for even partial "pasteurization" of poultry meat are far greater than the doses which have been deemed "safe" by any of the evidence or arguments provided by the FDA to date. The "massive" feeding studies of 5 megarad irradiated chicken are no more capable of assessing carcinogenic risk than are any of the other irradiated-food feeding studies the FDA has categorically dismissed before; all lack the dose-exaggeration factor essential to any valid toxicological test. All of the concerns of the presence of trace mutagens or carcinogens in foods irradiated at "low" doses of 100,000 rads are only greater at doses of one million rads, required for even partial Salmonella inactivation.

2. Major unresolved microbiological questions arise regarding the safety of gamma processing of

salmonella-contaminated poultry: much of the virulence of recent cases of salmonellosis has been attributed to the presence of antibiotic resistant strains of the pathogen, due in turn to the use of these antibiotics in the poultry industry (Cohen and Tauxe, 1986), the addition of a highly mutagenic processing procedure, namely, gamma irradiation, on poultry carcasses still containing low levels of antibiotics is an appalling scenario for the appearance in the irradiated food of new, antibiotic-resistant strains. This issue has received serious, but not adequate, attention in the scientific literature (Privet et al., 1971).

Enhancement of aflatoxin production

The FDA has also been quick to dismiss concerns that irradiation of Aspergillis flavus spores or the grains upon which this fungus can grow, can increase the production of the potent carcinogen aflatoxin (Federal Register, 4/18/86) citing and dismissing a single study on the subject. In fact (Table 3) there have been several studies showing serious aflatoxin--enhancement effects at or near the very doses proposed for the irradiation of grain.

Summary: rescind FDA approvals

In summary, the continuing research effort by our organization indicates clearly that recent and pending approvals of food irradiation processing by the FDA should be rescinded, and the same degree of caution now being expressed by several state and national agencies around the world be implemented on a federal level.

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Table 1 BIOASSAYS ON IRRADIATED ORGANIC MEDIA AND FOODS SHOWING POSITIVE MUTAGENICITY, CHROMOSOMAL DAMAGE, TERATOGENICITY, OR CYTOTOXICITY (page 1)

author(s)	date	irradiated material	observation	observed in
Kuzin & Kryukova	1961	plant leaves	chromosomal damage	plant embryos
Swaminathan et al.	1962	potato mash	chromosomal damage	barley embryos
Kuzin	1963	plant leaves	mutagenicity of extracts	plant cells
Swaminathan et al.	1963	culture medium	mutagenicity	drosophila
Chopra & Swaminathan	1964	potato mash	devel. abnormalities	barley embryos
Molin & Ehrenberg	1964	culture medium	cytotoxicity	bacteria
Berry et al.	1965	various sugars	cytotoxicity	human & mouse cells
Chopra	1965	culture medium	probable mutagenicity	bacteria
Holsten et al.	1965	coconut milk, sucrose	chromosomal damage	carrot explants
Parkash	1965	nucleic acids	mutagenicity	drosophila
Rinehart & Ratty	1965	culture medium	mutagenicity	drosophila
Frey & Pollard	1966	culture medium	mutagenicity	bacteria
Shaw & Hayes	1966	sucrose	chromosomal damage	human lymphocytes
Hills & Berry	1967	glucose	cytotoxcity	mouse fibroblasts
Hollowell & Littlefield	1967	plasma	chromosomal damage	human lymphocytes
Makinen et al.	1967	pineapple	chromosomal damage	onion roots
Parkash	1967	nucleic acids	mutagenicity	drosophila
Rinehart & Ratty	1967	nucleic acids	mutagenicity	drosophila
Rinehart & Ratty	1967	culture medium	mutagenicity	drosophila
Schubert et al.	1967	sucrose	cytotoxicity	bacteria
Steward et al.	1967	sucrose	cytotoxicity	carrot explants
Hollowell & Littlefield	1968	plasma	chromosomal damage	human leucocytes
Melette et al.	1968	wheat endosperm	mutagenicity	wheat
Ammirato & Steward	1969	sucrose	devel. abnormalities	plant root cells
Chopra	1969	culture medium	mutagenicity	bacteria
Moutschen-Dahmen et al.	1970	laboratory diet	preimplantation death	mouse
Schubert and Sanders	1971	various sugars	cytotoxicity	bacteria
Kopylov et al.	1972	potatoes	mutagenicity of extracts	mouse (sperm cells)
Kopylov et al.	1973	potatoes	mutagenicity	mouse
Bhaskaram & Sadasivian	1975	wheat	polyploidy	malnourished children
Vijayalaxmi & Sadasivan	1975	wheat	chromosomal damage	rat (bone marrow)
Vijayalaxmi	1975	wheat	polyploidy	rat (bone marrow)
Vijayalaxmi	1976	wheat	mutagenicity	mouse
Vijayalaxmi	1976	wheat	sperm count reduction	mouse
Vijayalaxmi	1976	wheat	polyploidy	mouse (bone marrow)
Vijayalaxmi	1976	wheat	aneuploidy	mouse (sperm cells)
Vijayalaxmi & Rao	1976	wheat	mutagenicity	rat
Vijayalaxmi & Rao	1976	wheat	sperm count reduction	rat

BIOASSAYS ON IRRADIATED ORGANIC MEDIA AND FOODS SHOWING POSITIVE MUTAGENICITY, CHROMOSOMAL DAMAGE, TERATOGENICITY, OR CYTOTOXICITY

author(s)	date	irradiated material	observation	observed in
Aiyar & Rao	1977	various sugars	mutagenicity	bacteria
FAO/IAEA/WHO	1977	potatoes	mutagenicity of extracts	mouse
Renner	1977	laboratory diet	polyploidy	hamster
Levina & Ivanov	1978	laboratory diet	autoimmune disease	rat
Vijayalaxmi	1978	wheat	low antibody levels	rat
Vijayalaxmi	1978	wheat	polyploidy, other effects	monkey
Wilmer et al.	1979	nucleic acids	mutagenicity	bacteria
Ivanov & Levina	1981	laboratory diet	testicular abnormalities	rat
Wilmer et al.	1981	nucleosides	mutagenicity	bacteria

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New York, NY (212)580-3889

able 2 IDENTIFICATION OF MUTAGENIC, CARCINOGENIC, OR CYTOTOXIC RADIOLYTIC PRODUCTS IN IRRADIATED ORGANIC MEDIA OR FOOD

uthor(s)	date	irradiated material	radiolytic product	comments
uzin	1965	plant matter, rat thymus, tyrosine	orthoquinones orthophenols	carcinogenic carcinogenic
erry et al.	1965	dextrose, fructose	glyoxal formaldehyde	mutagenic mutagenic
l Zeany	1980	buffalo meat	peroxides carbonyl compounds	mutagenic cytotoxic
ower & Wills	1986	benzpyrene, starch & oil mixtures	benzo(a)pyrenes quinones malonaldehyde lipid peroxides	carcinogenic carcinogenic mutagenic mutagenic
chubert et al.	1967	sucrose	hydroxyalkyl peroxides glyoxal	mutagenic mutagenic
chubert & Sanders	1971	D-glucose, D-fructose, D-mannose, D-rhamnose, D-galactose, D-fucose	alpha, beta-unsaturated carbonyl sugars	cytotoxic (toxicity increased upon heating irradiated solution)
teward et al.	1967	sucrose	formic acid	mutagenic
rey & Pollard	1966	minimal cell medium	hydrogen peroxide	mutagenic, generates secondary mutagens
hopra	1969	glucose	organic peroxides	mutagenic
uzin	1963	plant tissues	organic peroxides orthoquinones	mutagenic carcinogenic
ilmer et al.	1981	deoxy-D-ribose, D-ribose	hydrogen peroxide malonaldehyde carbonyl compounds	mutagenic mutagenic cytotoxic
rooks & Klamerth	1968	glucose	glyoxal malonyldialdehyde	mutagenic, binds to DNA mutagenic, binds to DNA

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Table 3 PUBLISHED STUDIES INDICATING INCREASED ~~ALFLATOXIN~~ AFLATOXIN PRODUCTION AFTER IRRADIATION

author	date	irradiated material	dose
Jemmali & Guilbot	1969	Aspergillis flavus spores	75 - 200 krad
Schindler & Noble	1970	Aspergillis flavus spores	20 - 500 krad
Priyadarshini & Tulpule	1976	wheat, potatoes, maize, sorghum, millet	10 - 75 krad
Priyadarshini & Tulpule	1979	wheat	50 - 250 krad
Schindler et al.	1980	Aspergillis flavus spores	75 - 450 krad

Accord Research and Educational Associates
New York, NY (212)580-3889
6/15/87

Alaska State Legislature
House

Official Business

REPRESENTATIVE RANDY PHILLIPS
HOUSE DISTRICT 15
(907) 465-4949

P.O. BOX V
State Capitol
Juneau, Alaska 99811

Memorandum

TO: Representative John Sund, Chairman
House Judiciary Committee

FROM: Representative Randy Phillips

DATE: March 10, 1988

RE: CSHB 388 (HESS)

Attached is a memorandum from Theresa L. Bannister, Legislative Counsel. This memorandum discusses the federal preemption clause, an issue raised by Representative Gruenberg at yesterday's committee meeting.

If you have any questions, please do not hesitate to contact me. Thank you for your assistance.

Attachment
cc: Rep. Fran Ulmer (w/attachment)
Rep. Sam Cotten (w/attachment)
Rep. Max Gruenberg (w/attachment)
Rep. Mike Navarre (w/attachment)
Rep. Ramona Barnes (w/attachment)
Rep. Robin Taylor (w/attachment)

STATE OF ALASKA
THE LEGISLATURE

LEGISLATIVE AFFAIRS AGENCY

POUCH Y STATE CAPITOL
JUNEAU ALASKA 99811
907 465 3800

M E M O R A N D U M March 10, 1988

SUBJECT: Federal preemption and CSHB 388(HESS)

TO: Representative Randy Phillips

FROM: Theresa L. Bannister
Legislative Counsel

You have requested an opinion whether the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (herein FDCA) preempts the prohibition in CSHB 388(HESS) against the sale of irradiated food. Although I do not believe that the issue is strictly black and white, in my opinion the FDCA would not preempt this prohibition.

At the outset, there is no specific preemption provision in the FDCA for this area; the FDCA does not explicitly address state laws other than for margarine. Next, the proposed prohibition does not stand as an obstacle to the accomplishment and execution of the purposes and objectives of the FDCA, since the goal of the FDCA relevant to this inquiry is to protect the individual from unsafe food, and the goal of the proposed law is the same. Finally, the proposed law does not directly conflict with the FDCA. Although the FDCA allows the use of irradiation in certain foods, it does not mandate the sale of these foods, but merely prescribes the conditions under which such things as irradiation may be safely used in certain foods. (See 21 U.S.C. 348).

In addition, I believe that a court would hesitate to preempt this proposed law for two reasons. The first reason is that the prohibition of the sale of irradiated food in the state falls within the traditional police powers of the state to protect the health and welfare of its inhabitants. The second reason is that there is a growing reluctance of courts to infer federal preemption of state laws. 55 U. S. Law Week 2226.

In conclusion, I believe that it is unlikely that a court would hold that the prohibition proposed by CSHB 388(HESS) against the sale of irradiated food to be preempted by the Federal Food, Drug, and Cosmetic Act.

If I may be of further assistance, please advise.

TLB:gc
WKG2:45

Alaska Center for the Environment

700 H Street, Suite 4 • Anchorage, Alaska 99501 • (907) 274-3621

March 8, 1988

To House Judiciary Committee Members:

Alaska Center for the Environment is a nonprofit citizens organization interested in environmental protection. We support HB 388, relating to irradiated food.

We understand that the US Department of Energy has contracted with the University to construct a demonstration plant to irradiate fish. We are concerned about the possibility of having this type of facility in Alaska because of the risks involved. These risks include transportation accidents, releases through leaks or emissions or spills of radioactive materials. The Cesium-137 that is to be used would likely contaminate groundwater if spilled to the ground because of its solubility in water. Also, how would it be decided where to locate such a facility--will seismicity, flooding and environmentally unsuited areas be excluded from consideration?

We support passage of HB 388 as a step towards discouraging the development of the food irradiation industry in Alaska. There is too much that is unknown about the molecular changes in food resulting from irradiation and the production of unique radiolytic products to be assured that it is a safe process. In fact, of 413 available studies on food irradiation, the FDA found only 5 studies that appear to support safety (from Final Report Task Group Irradiated Food, U.S. Department of Health. April 1982).

Sincerely,

Kristine Benson

Kristine Benson
Hazardous Waste Specialist

(7)

HOUSE COMMITTEE REPORT

Date referred: 1/22/88 FURTHER REFERRALS: Judiciary

DATE: 2-23-88

The Health, Education and Social Services Committee has considered HB 388

"An Act relating to irradiated food."

RECOMMENDS:

[X] replace with CS HB 388 (HESS) [X] the same title

[ ] attached amendment(s) [ ] a new title

[X] do pass

[ ] do not pass

[ ] no recommendation

[ ] individual recommendations

[ ] additional referral to the _____ Committee

ADOPTS: [ ] _____ letter of intent

ATTACHES NEW FISCAL NOTE(s):

[X] fiscal impact

[ ] zero fiscal note

[ ] zero with analysis

[ ] same as previous fiscal note published _____

[ ] same as previous zero fiscal note published _____

SIGNING DO PASS:

SIGNING OTHER RECOMMENDATIONS:

M. E. Greenberg / No Rec

Chairman's signature

POSITION PAPER/Department of Health & Social Services

Position Paper

HB 388

For an Act entitled: "An Act relating to irradiated food."

HB 388 prohibits the sale of irradiated food including spices and food that contains an irradiated ingredient unless the only irradiated ingredient is a spice. While it appears passage of this bill would have economic impact due to the long established practice of irradiating spices, the scope of this position paper is limited to the health considerations of irradiated food.

Background

The health aspects of irradiated food have been studied for many years. The Food and Drug Administration (FDA) has conducted exhaustive reviews of all available studies and has determined that irradiated food is safe for human consumption. The FDA has concluded there is no scientific evidence meeting FDA standards for toxicological studies that shows adverse effects on health from the consumption of irradiated food. Results of studies used to support claims of harmful effects have been rejected due to lack of adequate scientific controls or design, including radiation doses far in excess of those considered acceptable for food processing. In its conservative approach, the FDA has approved the irradiation of certain foods only, and it has limited the radiation doses to one-tenth of those shown to be safe. This position is supported by such diverse groups as the Council for Agricultural Science and Technology, the World Health Organization, the Food and Agricultural Organization of the United Nations, the American Medical Association, and the International Atomic Energy Agency.

In addition to the FDA, numerous national and international organizations recognized in health, food technology, and radiation safety have closely examined claims of harmful effects presently being made by those opposed to food irradiation. In every case, these organizations have judged irradiated food to be safe for human consumption.

Position

Without acceptable scientific evidence showing that irradiation is harmful to health, the department believes it is inappropriate to forbid the sale of irradiated food in the state. Proper labeling of irradiated foods will allow those opposed to it to exercise their choice in the foods they purchase.

The Department of Health and Social Services opposes passage of HB 388.

POSITION PAPER/Department of Health & Social Services

Recommended by: Elizabeth Ward

Elizabeth Ward, M.N.
Director
Division of Public Health

Date: February 2, 1988

Approved by: Myra M. Munson

Myra M. Munson
Commissioner
Department of Health and Social Services

Date: Feb 2 1988

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION: HB 388
PUBLISH DATE: _____

FISCAL NOTE

REQUEST:

Revision Date: 1/22/88
Title: An Act relating to irradiated food.
Sponsor: Phillips and Goll
Requestor: _____

Agency Affected: Health & Social Services
BRU: State Health Services
_____
Components: _____
_____

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER						
TOTAL	-0-	-0-	-0-	-0-	-0-	-0-

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

The enactment of HB 388 would have no direct fiscal impact on the Department of Health and Social Services.

Prepared by: Elizabeth Ward, Director Phone: 465-3090
Division: Public Health Date: 2-2-88

Approved by Commissioner: Mona M Munson Date: 2-2-88
Agency: Department of Health & Social Services

Distribution (by preparer):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

POSITION PAPER
DEPARTMENT OF ENVIRONMENTAL CONSERVATION

House Bill No. 388 February 2, 1988

"An act prohibiting the sale of irradiated food."

Department position:

The Department has not taken a position on this bill for the following reasons. The Department has no staff with training and experience in the irradiation of food. The Department's expertise regarding food products is inspecting the sanitary operations of food production facilities. There is a large amount of information and scientific data on this issue. Although review and analysis of the available data are beyond the Department's current capacity to effectively review and analyze, we are pleased to assist the committee in identifying useful information, including the following background.

FDA Requirements

The treatment of certain food products and spices with ionizing radiation is approved by the U.S. Food and Drug Administration (FDA). FDA has approved the following application dosages: for foods which can comprise more than 0.01% of the daily diet, the dosage cannot exceed 1 kilogray (KGy); for foods which can comprise less than 0.01% of the daily diet, dosage cannot exceed 50 KGy.

FDA Approved Sources of Irradiation

Approved irradiation sources include: radioactive isotopes (Cobalt-60 or Cesium-137) and machines (x-ray or electron beam).

FDA Foods Approved for Irradiation

FDA has approved the application of irradiation to the following foods: fruits/vegetables (slow growth and ripening and control insects); dried spices and herbs (kill insects and control microorganisms); pork (control trichinosis); white potatoes (growth and maturation inhibition); and wheat and wheat flour (control insects).

FDA Labeling Requirements

Labeling requirements have also been imposed by FDA to ensure that the consumer is aware that food they are consuming has been irradiated. Treated products contain a label statement that contains the international irradiation process logo (tulip) and

the statement "treated with radiation" or "treated by irradiation". On April 18, 1988 the requirement for the written warning is scheduled to be withdrawn. This action would leave only the international irradiation process logo on retail packages. FDA has informed DEC that this will probably not occur since the average consumer probably does not know what the logo symbolizes.

Enforcement

The department would enforce the provisions of this bill by inspecting food distributors, warehouses, and retail and wholesale outlets for food labeled with the federally required irradiation symbol and product statement. If irradiated food was found during the course of inspection, the department would embargo the product under the authority in 17.020.230 and require that it be destroyed or returned to an out-of-state distributor.

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION : HB 388
PUBLISH DATE : 1/22/88

FISCAL NOTE

REQUEST:

Revision Date: -
Title : An Act relating to irradiated food.
Sponsor : Peter Goll and Randy Phillips
Requestor : Randy Phillips

Agency Affected : Environmental Conservation
BRU : Environmental Health
Components : Sanitation

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES	-	14.9	14.9	14.9	14.9	14.9
TRAVEL	-	-	-	-	-	-
CONTRACTUAL	-	2.0	2.0	2.0	2.0	2.0
SUPPLIES	-	1.0	1.0	1.0	1.0	1.0
EQUIPMENT	-	-	-	-	-	-
LAND & STRUCTURES	-	-	-	-	-	-
GRANTS, CLAIMS	-	-	-	-	-	-
MISCELLANEOUS	-	-	-	-	-	-
TOTAL OPERATING	0	17.9	17.9	17.9	17.9	17.9
CAPITAL	0	0	0	0	0	0
REVENUE	0	0	0	0	0	0

FUNDING: (Thousands of Dollars)

GENERAL FUND	0	17.9	17.9	17.9	17.9	17.9
FEDERAL FUNDS	0	0	0	0	0	0
OTHER	0	0	0	0	0	0
TOTAL	0	17.9	17.9	17.9	17.9	17.9

POSITIONS:

FULL-TIME	-	-	-	-	-	-
PART-TIME	-	1	1	1	1	1
TEMPORARY	-	-	-	-	-	-

ANALYSIS : (Attach a separate page if necessary)

Attached.

Prepared by : Douglas C. Donegan
Phone : 465-2609
Division : Environmental Health
Date : 2/2/88

Approved by Commissioner : Dennis D. Kelso
Date : February 2, 1988
Agency : Environmental Conservation

Distribution (by preparer) :
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

STATE OF ALASKA

OFFICE OF THE GOVERNOR

BILL ANALYSIS

DEPARTMENT	DIVISION	BILL NUMBER	SPONSOR
Environmental Conservation	Environmental Health	HB 388	Peter Goll and Randy Phillips

SHORT TITLE OF BILL

"An Act relating to irradiated food"

DEPARTMENT POSITION: The passage of HB 388 would require that the Department expand it's inspection activities at approximately 500 retail markets to ensure that irradiated products were not being sold. The additional time per inspection is estimated to be approximately (Continued)

PREPARED BY	DATE	COMMISSIONER'S SIGNATURE	DATE
Douglas C. Donegan	2/2/88	Dennis D. Kelso	

SUMMARY

OTHER AGENCIES AFFECTED BY BILL	CONSTITUENT GROUP(S) AFFECTED BY BILL
ORGANIZATIONAL SUPPORT FOR BILL	**ORGANIZATIONAL OPPOSITION TO BILL**

FISCAL IMPACT: ☐ NONE ☐ FISCAL NOTE ATTACHED

BACKGROUND/LEGISLATIVE INTENT

ANALYSIS OF BILL/PROGRAM EFFECTS

AMENDMENTS PROPOSED

PLEASE ATTACH A SEPARATE SHEET FOR ADDITIONAL COMMENTS OR ANALYSIS.

01-009 (Rev. 12/83)

one (1) hour per inspection. These facilities are inspected once per year.

The Department would begin inspecting 51 retail markets in the Municipality of Anchorage, which are not currently inspected by the department. It is estimated that the inspection of these markets would be approximately 2 hours including travel time.

This inspection effort would amount to a total of 602 hours/year or about four months/year.

Position Title	No. of Positions	Range/Step	Barg. Unit
Environmental Sanitarian II	1	16/A	G

Time Status	Staff Months	Location	Election District
F	Four (4)	Anchorage, Ak.	7

Type of Expenditure		Amount
1	2	3
Salary	11.2	
Benefits	3.7	
Premium Pay	-	
Other	-	
Total Personal Services		14.9
Travel		-
Contractual		2.0
Commodities		1.0
Equipment		-
Other		-
Total Cost		17.9

Funding Source for Total Cost		
Federal Receipts	1002	-
G. F. Match	1003	-
General Fund	1004	17.9
GF Program Receipts	1005	-
Other		-

Justification

This position is required to support the implementation of HB 388 "An Act relating to irradiated food." Approximately 500 retail markets would be inspected to ensure that prohibited products were not being sold. All retail markets would be contacted and notified of the new law. It is estimated that the inspection of these facilities would require approximately 2 hours each, including travel time.

The additional inspection effort would amount to a total of 602 hours per year or about four months per year.

Request For New Position

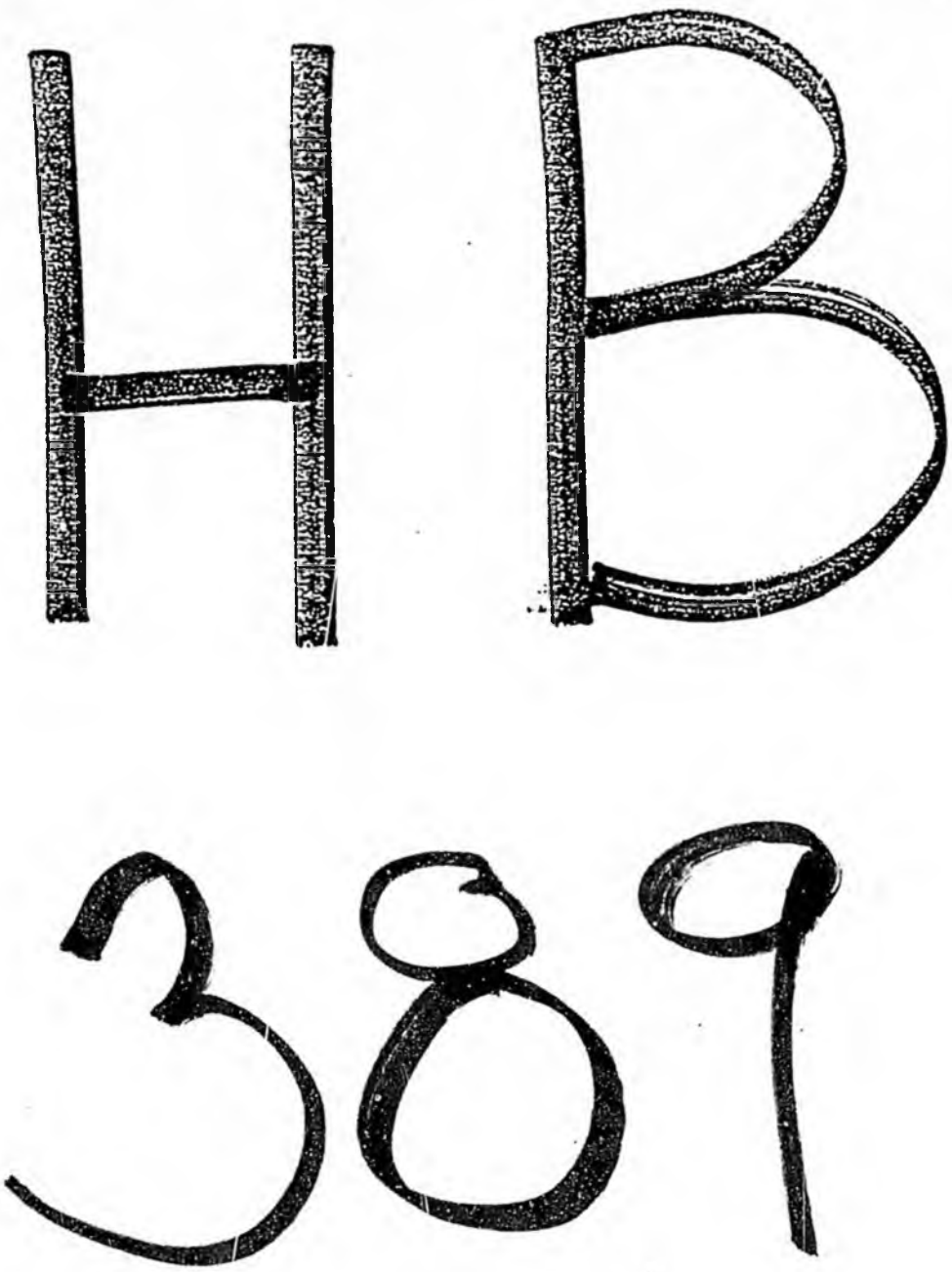
Agency Environmental Conservation

BRU Environmental Health

Component Sanitation

Revised Date

FY 89


HB
389

STATE OF ALASKA
THE LEGISLATURE

POUCH Y · STATE CAPITOL
JUNEAU, ALASKA 99811
907·465·3800

LEGISLATIVE AFFAIRS AGENCY

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May, 1988

Copies of minutes listed below were originally included in this file. The minutes are available on the STAIRS database CMPR. In order to save space copies of minutes have not been left in the files.

Mary Van Nimwegen

House Judiciary:

3-1-88

3-8-88

3-23-88

(7)

HOUSE COMMITTEE REPORT

Date referred: 2/1/88 FURTHER REFERRALS: Finance

DATE: March 23, 1988

The Judiciary Committee has considered HB 389

"An Act relating to recovery of state costs for oil and hazardous substance releases; and providing for an effective date."

RECOMMENDS:

[✓] replace with CS HB 389 (Jud) [ ] the same title

[ ] attached amendment(s) [ ] a new title

- [✓] do pass
- [ ] do not pass
- [ ] no recommendation
- [ ] individual recommendations
- [ ] additional referral to the _____ Committee

ADOPTS: [ ] _____ letter of intent

ATTACHES NEW FISCAL NOTE(s):

- [ ] fiscal impact
- [ ] zero fiscal note
- [ ] zero with analysis
- [ ] same as previous fiscal note published _____
- [✓] same as previous zero fiscal note published 2/1/88

SIGNING DO PASS:

Mike Navarro

Jim Cates

SIGNING OTHER RECOMMENDATIONS:

Robin L. Taylor (NO Rec.)

Chairman's signature

go0298hB
Hein
3/7/88

Original sponsors: Rules/Governor

Adopted

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE BILL NO. 389 (Judiciary)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to recovery of state costs for oil and hazardous substance releases; and providing for an effective date."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 46.08 is amended by adding a new section to read:

Sec. 46.08.075. LIENS AGAINST PROPERTY AS SECURITY FOR STATE EXPENDITURES. (a) The state has a lien for expenditures by the state from the oil and hazardous substance release response fund or from any other state fund, for the containment, cleanup, or mitigation of oil or hazardous substance spills, against all property owned by a person who is determined by the commissioner to be liable for the expenditures under this chapter, AS 46.03, AS 46.04, 42 U.S.C. 9607, or other state or federal law. The lien includes interest, at the maximum rate allowable under AS 45.45.010(a), from the date of the expenditures.

(b) A lien established under this section against real property is not effective unless

(1) a certificate of lien is recorded in the district recorder's office for the district in which the property is located, describing the property and stating the amount of the lien, the name of the owner as grantor, and, if known, the name of the person causing the oil or hazardous substance release; and

(2) the commissioner sends a copy of the certificate by certified mail to the persons described in (1) of this subsection and to all other persons of record holding an interest in the property.

(c) When any amount with respect to which a lien has been recorded under this section has been paid or reduced, the commissioner shall, upon request of the property owner, issue a certificate discharging or partially releasing the lien. That certificate may be recorded in the office where the certificate of lien was recorded.

(d) A person with an ownership interest in property against which a lien is recorded may bring an action in the superior court to require that the lien be released. The lien shall be released if the court finds that the owner of the property is not liable for the costs of the state in connection with containment, cleanup, or mitigation of the oil or hazardous substance release.

* Sec. 2. This Act takes effect immediately under AS 01.10.070(c).

5-1465B
Hein
3/11/88

Original sponsors: Davis, Koponen, Navarre, et al.

Adopted

IN THE HOUSE BY THE RESOURCES COMMITTEE

CS FOR HOUSE BILL NO. 459 (Resources)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to liability for releases of hazardous substances."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 46.03.822 is repealed and reenacted to read:

Sec. 46.03.822. STRICT LIABILITY FOR THE RELEASE OF HAZARDOUS SUBSTANCES. (a) The following persons are strictly liable, jointly and severally, for damages to persons or property, public or private, including damage to the natural resources of the state and the costs of response, containment, removal, or remedial action incurred by the state or a municipality, resulting from a release of a hazardous substance or, with respect to response costs, the substantial threat of a release of a hazardous substance:

(1) the owner and the person having control over the hazardous substance at the time of the release or threatened release;

(2) the owner and the operator of the facility or vessel from which the release occurred or was threatened to occur; in the case of an abandoned facility or vessel, the owner, the operator, and any other person who controlled activities at the facility or on the vessel immediately before the abandonment;

(3) a person who owned or operated the facility or vessel from which the release occurred or was threatened to occur at the time the hazardous substance was received by the facility or vessel;

(4) a person who owned the hazardous substance and who arranged for disposal or treatment of the substance by another party

or entity, or arranged with a transporter to transport the substance for disposal or treatment by another party or entity, at a facility or incineration vessel that contained the substance and that was owned or operated by the party or entity; and

(5) a person who transported or accepted the hazardous substance for transport to the facility, vessel, or site from which the release occurred or was threatened to occur, if the person selected the facility, vessel, or site.

(b) In an action to recover damages, a person otherwise liable is relieved from strict liability if the person proves by clear and convincing evidence

(1) that the release or threatened release of the hazardous substance to which the damages relate occurred solely as a result of

(A) an act of war;

(B) an intentional or negligent act of a third party, other than a party or its employees in privity of contract with, or employed by, the person, and that the person

(i) exercised due care with respect to the hazardous substance; and

(ii) took reasonable precautions against the act of the third party and against the consequences of the act; or

(C) an act of God; and

(2) in relation to (1)(B) or (C) of this subsection, that the person, within a reasonable period of time after the act occurred,

(A) discovered the release or threatened release of the hazardous substance; and

(B) began operations to contain and clean up the hazardous substance.

(c) For purposes of (b)(1)(B) of this section, a third party or an employee of a third party is in privity of contract with the person who is otherwise liable if the third party or employee and the person are parties to a land contract, deed, or other instrument transferring title or possession, unless the real property on which the facility in question is located was acquired by the person after the disposal or placement of the hazardous substance on, in, or at the facility, and the person by a preponderance of the evidence establishes that the person has satisfied the requirements of (b)(1)(B) of this section and establishes one or more of the following circumstances:

(1) at the time the person acquired the facility the person did not know and had no reason to know that a hazardous substance that is the subject of the release or threatened release was disposed of on, in, or at the facility;

(2) the person is a government entity that acquired the facility by escheat, or through another involuntary transfer or acquisition, or through the exercise of eminent domain authority by purchase or condemnation;

(3) the person acquired the facility by inheritance or bequest.

(d) To establish that a person had no reason to know that the hazardous substance was disposed of, on, in, or at the facility, as provided in (c)(1) of this section, the person must have undertaken, at the time of acquisition, all appropriate inquiries into the previous ownership and uses of the property consistent with good commercial or customary practice in an effort to minimize liability. For purposes of this subsection the court shall take into account any specialized knowledge or experience the person has; the relationship of the purchase price to the value of the property if uncontaminated;

commonly known or reasonably ascertainable information about the property; the obviousness of the presence or likely presence of contamination at the property; and the ability to detect contamination by appropriate inspection.

(e) This section does not diminish the liability of a person who previously owned or operated a facility and who would otherwise be liable; however, if the person obtained actual knowledge of the release or threatened release of a hazardous substance at the facility and subsequently transferred ownership to another without disclosing that knowledge, the person is liable under (a)(2) of this section, and a defense under (b)(1)(B) of this section is not available to the person.

(f) This section does not affect the liability of a person who, by an act or omission, caused or contributed to the release or threatened release of a hazardous substance that is the subject of the action relating to the facility.

(g) An indemnification, hold harmless, or similar agreement or conveyance is not effective to transfer liability under this section from the owner or operator of a vessel or facility or from a person who may be liable for a release or substantial threat of a release under this section. This subsection does not bar an agreement to insure, hold harmless, or indemnify a party to the agreement for liability under this section. This subsection does not bar a cause of action that an owner or operator or other person subject to liability under this section, or a guarantor, has or would have, by reason of subrogation or otherwise against a person.

* Sec. 2. AS 46.03.826 is amended by adding a new paragraph to read:

(8) "facility" includes a

(A) building; structure; installation; equipment; pipe

or pipeline, including a pipe into a sewer or publicly owned treatment works; well; pit; pond; lagoon; impoundment; ditch; landfill; storage container; motor vehicle; rolling stock; or aircraft; or

(B) site or area at which a hazardous substance has been deposited, stored, disposed of, placed, or otherwise located.

Offered: 3/24/88
Referred: Finance

go0298hB

current bill

bill file

(1)

Original sponsors: Rules/Governor

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE BILL NO. 389 (Judiciary)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to recovery of state costs for oil and hazardous substance releases; and providing for an effective date."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* Section 1. AS 46.08 is amended by adding a new section to read:

Sec. 46.08.075. LIENS AGAINST PROPERTY AS SECURITY FOR STATE EXPENDITURES. (a) The state has a lien for expenditures by the state from the oil and hazardous substance release response fund or from any other state fund, for the containment, cleanup, or mitigation of oil or hazardous substance spills, against all property owned by a person who is determined by the commissioner to be liable for the expenditures under this chapter, AS 46.03, AS 46.04, 42 U.S.C. 9607, or other state or federal law. The lien includes interest, at the maximum rate allowable under AS 45.45.010(a), from the date of the expenditures.

(b) A lien established under this section against real property is not effective unless

(1) a certificate of lien is recorded in the district recorder's office for the district in which the property is located, describing the property and stating the amount of the lien, the name of the owner as grantor, and, if known, the name of the person causing the oil or hazardous substance release; and

(2) the commissioner sends a copy of the certificate by certified mail to the persons described in (1) of this subsection and to all other persons of record holding an interest in the property.

(c) When any amount with respect to which a lien has been recorded under this section has been paid or reduced, the commissioner shall, upon request of the property owner, issue a certificate discharging or partially releasing the lien. That certificate may be recorded in the office where the certificate of lien was recorded.

(d) A person with an ownership interest in property against which a lien is recorded may bring an action in the superior court to require that the lien be released. The lien shall be released if the court finds that the owner of the property is not liable for the costs of the state in connection with containment, cleanup, or mitigation of the oil or hazardous substance release.

* Sec. 2. This Act takes effect immediately under AS 01.10.070(c).

Introduced: 1/22/88
Referred: Resources, Judiciary and Finance

go00298h

IN THE HOUSE

BY THE RULES COMMITTEE BY REQUEST OF THE GOVERNOR

HOUSE BILL NO. 389

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

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(b) A lien established under this section against real property is not effective unless (1) a certificate of lien is recorded in the district recorder's office for the district in which the property is located, describing the property and stating the amount of the lien, the name of the owner as grantor, and, if known, th name of the person causing the oil or hazardous substance release; and (2) the commissioner mails a copy of the certificate to the persons described in (1) of this subsection and to all other persons of record holding an interest in the property.

(c) A lien established under this section is superior to a transfer, mortgage, attachment, claim, demand, or other encumbrance established on or after the ~~effective~~ date of this Act, in any manner affecting the property. This subsection does not apply to real property that consists exclusively of residential real property. The commissioner may adopt regulations defining "residential real property" for the purposes of this section.

(d) For property consisting exclusively of residential real property, a lien established under this section is superior to a transfer, mortgage, attachment, claim, demand, or other encumbrance on that property recorded after a certificate of lien is recorded under this section on that property.

(e) When any amount, with respect to which a lien has been recorded under this section, has been paid or reduced, the commissioner shall, upon request of the property owner, issue a certificate discharging or partially releasing the lien. That certificate may be recorded in the office where the certificate of lien was recorded.

(f) A person with an ownership interest in property against which a lien is recorded may bring an action in the superior court to require that the lien be released. The lien must be released if the court finds that the owner of the property is not liable for the costs of the state in connection with containment, cleanup, or mitigation of the oil or hazardous substance release.

* Sec. 2. This Act takes effect immediately under AS 01.10.070(c).

containment
clean up
mitigation

Introduced: 1/22/88
Referred: Resources, Judiciary and Finance

go00298h

BY THE RULES COMMITTEE BY REQUEST OF THE GOVERNOR

IN THE HOUSE

HOUSE BILL NO. 389

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

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(b) A lien established under this section against real property is not effective unless (1) a certificate of lien is recorded in the district recorder's office for the district in which the property is located, describing the property and stating the amount of the lien, the name of the owner as grantor, and, if known, the name of the person causing the oil or hazardous substance release; and (2) the commissioner mails a copy of the certificate to the persons described in (1) of this subsection and to all other persons of record holding an interest in the property.

Philosophy:

The battle here is between State and other secured general creditors not between State and "responsible parties"

Initial entry permits??

(c) A lien established under this section is superior to a transfer, mortgage, attachment, claim, demand, or other encumbrance established on or after the effective date of this Act, in any manner affecting the property. This subsection does not apply to real property that consists exclusively of residential real property. The commissioner may adopt regulations defining "residential real property" for the purposes of this section.

??? ???

(d) For property consisting exclusively of residential real property, a lien established under this section is superior to a transfer, mortgage, attachment, claim, demand, or other encumbrance on that property recorded after a certificate of lien is recorded under this section on that property.

(e) When any amount, with respect to which a lien has been recorded under this section, has been paid or reduced, the commissioner shall, upon request of the property owner, issue a certificate discharging or partially releasing the lien. That certificate may be recorded in the office where the certificate of lien was recorded.

release lien

(f) A person with an ownership interest in property against which a lien is recorded may bring an action in the superior court to require that the lien be released. The lien must be released if the court finds that the owner of the property is not liable for the costs of the state in connection with containment, cleanup, or mitigation of the oil or hazardous substance release.

* Sec. 2. This Act takes effect immediately under AS 01.10.070(c).

- or has acquired the lien.

- what about continuing leakage.

How does this affect purchase of property ⇒ problems with title (exceptions)

should clean up costs come ahead of other secured or general creditors?

Original sponsors: Rules/Governor

IN THE HOUSE BY THE JUDICIARY COMMITTEE

CS FOR HOUSE BILL NO. 389 (Judiciary)

IN THE LEGISLATURE OF THE STATE OF ALASKA

FIFTEENTH LEGISLATURE - SECOND SESSION

A BILL

For an Act entitled: "An Act relating to recovery of state costs for oil and hazardous substance releases; and providing for an effective date."

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(b) A lien established under this section against real property is not effective unless

(1) a certificate of lien is recorded in the district recorder's office for the district in which the property is located, describing the property and stating the amount of the lien, the name of the owner as grantor, and, if known, the name of the person causing the oil or hazardous substance release; and

(2) the commissioner sends a copy of the certificate by certified mail to the persons described in (1) of this subsection and to all other persons of record holding an interest in the property.

(c) When any amount with respect to which a lien has been recorded under this section has been paid or reduced, the commissioner shall, upon request of the property owner, issue a certificate discharging or partially releasing the lien. That certificate may be recorded in the office where the certificate of lien was recorded.

(d) A person with an ownership interest in property against which a lien is recorded may bring an action in the superior court to require that the lien be released. The lien shall be released if the court finds that the owner of the property is not liable for the costs of the state in connection with containment, cleanup, or mitigation of the oil or hazardous substance release.

* Sec. 2. This Act takes effect immediately under AS 01.10.070(c).

Adopted

SUBSTITUTE LANGUAGE AT "A":

(4) a person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances; and

NEW LANGUAGE AT "B":

(5)(1) The term "privity of contract" in (b)(1)(B) of this section includes, but is not limited to, being a party to land contracts, deeds or other instruments transferring title or possession, unless the real property on which the facility concerned is located was acquired by the defendant after the disposal or placement of the hazardous substance on, in, or at the facility, and one or more of the circumstances described in clause (i), (ii), or (iii) is also established by the defendant by a preponderance of the evidence:

(i) At the time the defendant acquired the facility the defendant did not know and had no reason to know that any hazardous substance which is the subject of the release or threatened release was disposed of on, in, or at the facility.

(ii) The defendant is a government entity which acquired the facility by escheat, or through any other involuntary transfer or acquisition, or through the exercise of eminent domain authority by purchase or condemnation.

(iii) The defendant acquired the facility by inheritance or bequest.

In addition to establishing the foregoing, the defendant must establish that he has satisfied the requirements of subsection ~~107~~(b)(3)(A) and (B).

2(A) (B)

(2)(B) To establish that the defendant had no reason to know, as provided in clause (i) of subparagraph (A) of this paragraph, the defendant must have undertaken, at the time of acquisition, all appropriate inquiry into the previous ownership and uses of the property consistent with good commercial or customary practice in an effort to minimize liability. For purposes of the preceding sentence the court shall take into account any specialized knowledge or experience on the part of the defendant, the relationship of the purchase price to the value of the property if uncontaminated, commonly known or reasonably ascertainable information about the property, the obviousness of the presence or likely presence of contamination at the property, and the ability to detect such contamination by appropriate inspection.

(3)(C) Nothing in this paragraph or in section 107(b)(3) shall diminish the liability of any previous owner or operator of such facility who would otherwise be liable under this Act. Notwithstanding this paragraph, if the defendant obtained actual knowledge of the release or threatened release of a hazardous substance at such facility when the defendant owned the real property and then subsequently transferred ownership of the property to another person without disclosing such knowledge, such defendant shall be treated as liable under section 107(a)(1) and no defense under section 107(b)(3) shall be available to such defendant.

4(D) Nothing in this paragraph shall affect the liability under this Act of a defendant who, by any act or omission, caused or contributed to the release or threatened release of a hazardous substance which is the subject of the action relating to the facility.

water by the department of health and environment or the federal environmental protection agency under the authority of the Safe Drinking Water Act. All such tests shall be paid for by such county. [Acts 1983, ch. 423, § 8.]

Compiler's Notes. Concerning the Safe Drinking Water Act referred to in subsection (b), the federal act by that name is compiled in U.S.C. in various sections throughout titles 5, 21, and 42, and the Tennessee act of the same name is codified in part 7, chapter 13 of this title.

Section to Section References. This section is referred to in § 68-46-210.

68-46-209. Liens on property. — (a) Whenever a hazardous substance site is placed on the list of hazardous substance sites pursuant to § 68-46-206(e), or whenever the commissioner otherwise begins to expend money for investigation, identification, containment or clean up of a particular site under this part, the commissioner may file a notice with the office of the register of deeds of the county in which the property lies.

(b) Within one (1) year after the completion of a project to contain or clean up the hazardous substance at a particular site under this part, the commissioner shall itemize the money so expended and shall file a statement thereof in the office of the register of deeds of the county in which the property lies, together with notarized appraisals by an independent appraiser of the value of the property before and after the clean up work performed at the site, if the money so expended shall result in a significant increase in property values. Such statement shall constitute a lien upon such land. The lien shall not exceed the amount determined by the appraisal to be the increase in the market value of the property as a result of the clean up work.

(c) If the property owner is aggrieved by the amount of the lien filed under subsection (a), the property owner may cause another appraisal to be performed by an independent appraiser and may submit the matter to the chancery court of the county in which the property is located to determine the appropriate amount of the lien. A decision of that court may be appealed according to the Tennessee Rules of Appellate Procedure.

(d) The lien provided in this section shall be entered in the records of the register of deeds of the county in which the property lies. Such statements shall constitute a lien upon such property as of the date the notice is filed pursuant to subsection (a), and shall have priority as a lien second only to tax liens. Such a lien shall be satisfied to the extent of the value of the consideration received at the time of transfer of ownership, and if the lien is not fully satisfied at the time of transfer, it shall remain a lien on the property until it is fully satisfied.

(e) A form of notice substantially as follows is sufficient to comply with subsection (a):

NOTICE OF LIEN UNDER
HAZARDOUS WASTE MANAGEMENT ACT OF 1983

Name of titleholder(s) .....
Property address .....
Description of property subject to possible lien sufficient to identify such property .....

Date, signature, and address of the Commissioner or his authorized designee .....

The register of deeds shall note the date and time of filing, and an appropriate registration number, and shall record the notice in the lien book in the office of the register.

(f) The effective date of all prior liens claimed under this chapter shall be unaffected by the 1986 amendment to this section if a notice is filed in accordance with subsection (a) of this section on or before December 31, 1986, which notice shall set forth, in addition to the information required by subsection (e) hereof, the claimed effective date of the lien if earlier than the date of the filing of the notice. After December 31, 1986, all claimed liens shall be effective as of the date the notice is filed pursuant to subsection (a). [Acts 1983, ch. 423, § 9; 1986, ch. 528, § 1.]

Compiler's Notes. Acts 1986, ch. 528, § 1, added (a), (e), and (f) and amended (d).

68-46-210. Responsible waste disposal incentive fund. — (a) There is created a special agency account in the general fund to be known as the "responsible waste disposal incentive fund."

(b) There is appropriated to the responsible waste disposal incentive fund the sum of five hundred thousand dollars ($500,000) for fiscal year 1983-1984 and there shall be appropriated the sum of one million five hundred thousand dollars ($1,500,000) for fiscal year 1984-1985.

(c) Interest accruing on investments and deposits of such fund shall be returned to it and remain a part of such fund.

(d) Any unencumbered and any unexpended balance of this fund remaining at the end of any fiscal year shall not revert to the general fund, but shall be carried forward until expended in accordance with the provisions of this section.

(e)(1) The board shall promulgate rules and regulations in accordance with the provisions of the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, to establish eligibility requirements for a local government to receive the money deposited in the responsible waste disposal incentive fund.

(2) At a minimum, for a local government to be eligible to receive such funds, the commercial facility must be located within the jurisdiction of such local government, such facility must have a permit to operate pursuant to the provisions of § 68-46-108, such facility must be constructed and operational and the following standards must be met:

(A) The facility is multi-purpose with both land disposal capability and facilities for advanced technology, high-temperature thermal treatment;

(B) The facility has a minimum design capacity to operate for twenty (20) years;

(C) The facility is operated pursuant to the provisions of part 1 of this chapter; and

(D) The local government with jurisdiction over the facility does not have any zoning requirement, subdivision regulation, ordinance, regulation or

compel cleanup or containment consistent with regulations and guidelines established by the secretary.

E. (1) When a site has been declared an abandoned hazardous waste site, the secretary is authorized to undertake the physical control, containment and cleanup, or closure of the abandoned hazardous waste site and may retain personnel for these purposes who shall operate under his direction.

(2) In all cases in which the secretary proposes to treat, store, or dispose of hazardous wastes at the abandoned hazardous waste site, he shall prepare a closure plan setting forth how the site will be closed. The secretary shall provide an opportunity for the public to submit comments about the plan. The secretary shall provide adequate notice to the public of any public hearings on the closure plan by placing a notice in the general circulation newspaper of the parish in which the hearing is to be held. If the secretary determines that immediate action is required to secure the site or dispose of any waste in order to protect the health or safety of persons affected by the site or its contents or to protect the environment, he may take such action prior to submission of the plan and may subsequently submit a plan detailing emergency actions taken and those actions which he will be taking in the future.

(3) The secretary shall have authority to implement the closure plan and to take all actions including erecting fences, signs, gates, levees, and monitoring devices as are reasonably necessary to secure the site and prevent unauthorized or inadvertent entry.

F. (1) The secretary, by recording the declaration of abandonment in the mortgage records of the parish where the property is located, may create a lien against property declared to be abandoned to the extent of the expenditures by the state necessary to remedy the problem or to the extent of the appraised value after said expenditures, whichever is less. The secretary may provide in the declaration that the lien is limited to certain portions of property declared to be abandoned and may provide that a lien shall not be recorded against property of a person that the commission finds was in no way responsible for the spill or accident causing the damage requiring the expenditure of money from the fund. The filing of a sworn statement of the amount expended perfects the lien retroactively to the date of the recordation of the declaration.

(2) Subsequent to a declaration of abandonment, a person whose property has been declared to be abandoned and against which a lien has been created thereby may apply to the secretary or file an action in the district court to require that the clerk erase the lien from the records if the secretary or court finds that the spill was in no way caused by any action or negligence on the part of the person who is the owner of the property subject to the lien or may file an action to have the debt reduced to the appraised value of the property.

Added by Acts 1984, No. 674, § 1.

§ 1149.7. Hazardous Waste Assessment Report; requirements; submission

A. The secretary is hereby authorized and mandated to develop a comprehensive evaluation of hazardous waste in Louisiana, and to issue such evaluation in the form of a report as provided for herein. The office of solid and hazardous waste shall assist the secretary in the development and on-going update of the report.

B. Prior to January 31, 1986, the secretary shall present a report as authorized in Subsection A of this Section to the Senate and House Natural Resources Committees. The report shall, at a minimum, provide the following information:

(1) An inventory of the known hazardous waste sites in Louisiana, including:

(a) The types of wastes as determined by the secretary to be present in the waste sites.

(b) An estimate of the amount of each type of waste in a waste site as may be reasonably determined by the secretary.

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Code of Massachusetts Regulations

Department of environmental quality engineering,

Availability of public records to general public, see 310 CMR 3.10.

When trade secrets may be disclosed by department, see 310 CMR 3.21.

§ 13. Judgment; interest; lien on property persons liable

Any liability to the commonwealth under this chapter shall constitute a debt to the commonwealth. Any such debt, together with interest thereon at the rate of twelve per cent per annum from the date such debt becomes due, shall constitute a lien on all property owned by persons liable under this chapter when a statement of claim naming such persons is recorded or filed. If the site described in such statement comprises real property, the statement shall be recorded in each registry of deeds in the commonwealth and shall also be registered in each registry district in which any person named in such statement of claim holds record title to registered land as shown on the current index of registered land owners in such district. The land court certificate number of each such owner shall be noted on the statement when presented for recording and each assistant recorder, upon receipt of such statement, shall note such statement on the owner's certificate of title. In the case of personal property, whether tangible or intangible, the statement shall be filed in accordance with the provisions of section 9–401 of chapter one hundred and six. Any lien recorded, registered or filed pursuant to this section shall have priority over any encumbrance theretofore recorded, registered or filed with respect to any site, other than real property the greater part of which is devoted to single or multi-family housing, described in such statement of claim, but as to all other real property shall be subject to encumbrances or other interests recorded, registered or filed prior to the record, registration or filing of such statement, and as to all other personal property shall be subject to the priority rules of said chapter one hundred and six. Such lien, other than a lien on real property the greater part of which is devoted to single or multi-family housing, shall continue in force with respect to any particular real or personal property until a release of the lien signed by the commissioner is recorded registered or filed in the place where the statement of claim as to such property affected by the lien was recorded, registered or filed. In addition to discretionary releases of liens, the commissioner shall forthwith issue such a release in any case where the debt for which such lien attached, together with interest and costs thereon, has been paid or legally abated. This section shall not apply to any property, real or personal, tangible or intangible, any money, fees, charges, revenues or otherwise, owned, payable to or by, held in trust by or for, or otherwise owned, operated or managed by the Massachusetts Municipal Wholesale Electric Company established pursuant to chapter seven hundred and seventy-five of the acts of nineteen hundred and seventy-five, Massachusetts municipal light departments organized under chapter one hundred and sixty-four or any other special law, or with respect to any property real or personal whatsoever of municipal light departments administered pursuant to chapters forty-four and one hundred and sixty-four A. Notwithstanding the foregoing, the aforesaid Massachusetts Municipal Wholesale Electric Company and Municipal Light Departments shall use their authority as provided by applicable statutes to assess, contain, or remove any such oil or hazardous material release for which they are responsible under chapter twenty-one E.

Added by St.1983, c. 7, § 5. Amended by St.1983, c. 573, § 3.

1983 Amendment. St.1983, c. 573, § 3, an emergency act, approved Dec. 15, 1983, and by § 4 made effective as of March 24, 1983, in the second sentence, substituted "owned by" for ", and rights to property, real and personal, presently owned or after acquired, of the", substituted "when" for "if" and "naming such persons is recorded or filed" for ", describing the property subject to the lien and signed by the commissioner, is filed within ninety days after the incurrence of costs and expenses"; rewrote the third sentence, which prior thereto read: "In the case of real property, the statement shall be filed in accepted and recorded by the appropriate registry of deeds."; inserted the fourth sentence designated the former first and second sentences of the second paragraph as the sixth and seventh

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n (c) of section 22a-56. Any
is section shall be deposited in
r this section and shall be used
issioner pursuant to subsection
or mitigation.

P.A. 76-9, S. 1, 2; P.A. 79-605, S. 5, 17;
1; 84-370, S. 1, 6; P.A. 85-177, S. 1, 2;

to study pesticide pollution of groundwater

, added proviso allowing assessment of treble
water resources commission and its chairman
l that provisions applicable in cases where
, substituted "negligently caused" for "gross
e and one-half times the costs and expenses
bility to cases where damages would exceed
ses to emergencies, to uncontrolled losses of
ites, deleted provision setting forth allocation
mended Subsec. (d) to authorize expenditures
nse, Compensation and Liability Act of 1980,
waste disposal sites, and to specify limits on
cifically subjected hazardous waste owned by
otial threat to health or environment, to the
d by requiring that not more than $80,000 be
.A. 84-81 amended Subsec. (d) by limiting
r costs for short-term provision and capital
uthorization of funds for the hazardous waste
l years involved and by imposing limit on
07 amended Subsec. (d) by deleting language
ble drinking water, requiring the commissioner
stablishing the cap on the amount that can be
the limit on expenditures under Subdiv. (5) to
.5) of Subsec. (d) by authorizing expenditures
orizing double damages if pollution was wilful;
y the Hazardous Waste Management Service in
f potable drinking water and a pesticide study

ne second Wednesday after the
assembly, the commissioner of
joint standing committee of the
g to the environment, which sets
(1) the amount of income to and
tablished by section 22a-451, and
ding the status of said fund for the

bursement for containment or
issions. (a) Any person, firm,
s or otherwise mitigates the effects
or gaseous products or hazardous
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o reimbursement from any person,
for such containment, removal, or
quids or solid, liquid or gaseous
ation or other emergency resulted
, firm or corporation. When such

pollution or contamination or emergency results from the joint negligence or other actions of two or more persons, firms or corporations, each shall be liable to the others for a pro rata share of the costs of containing, and removing or otherwise mitigating the effects of the same and for all damage caused thereby.

(b) No person, firm or corporation which renders assistance or advice in mitigating or attempting to mitigate the effects of an actual or threatened discharge of oil or petroleum or chemical liquids or solid, liquid or gaseous products or hazardous materials or which assists in preventing, cleaning-up or disposing of any such discharge shall be held liable, notwithstanding any other provision of law, for civil damages as a result of any act or omission by him in rendering such assistance or advice, except acts or omissions amounting to gross negligence or wilful or wanton misconduct, unless he is compensated for such assistance or advice for more than actual expenses. For the purpose of this subsection, "discharge" means spillage, uncontrolled loss, seepage or filtration and "hazardous materials" means any material or substance designated as such by any state or federal law or regulation.

(c) The immunity provided in this section shall not apply to (1) any person, firm or corporation responsible for such discharge, or under a duty to mitigate the effects of such discharge, (2) any agency or instrumentality of such person, firm or corporation or (3) negligence in the operation of a motor vehicle.

(1969, P.A. 765, S. 5; 1971, P.A. 872, S. 105; P.A. 79-605, S. 6, 17; P.A. 83-374, S. 1, 2; P.A. 86-239, S. 12, 14.)

History: 1971 act replaced reference to water resources commission in Subsec. (b) with reference to environmental protection commissioner; P.A. 79-605 clarified provisions by adding references to containment or mitigation of pollutants, to "solid, liquid or gaseous" products, to hazardous wastes, etc.; Sec. 25-54ff transferred to Sec. 22a-452 in 1983; P.A. 83-374 replaced existing provisions re liability of persons, firms and corporations assisting in cleaning up or disposing of discharges with new provisions and defined "discharge" and "hazardous material" and added Subsec. (c), excluding from the immunities provided those responsible for the discharge or those who are negligent in the operation of a motor vehicle; P.A. 86-239 amended Subsec. (a) by authorizing municipalities to be reimbursed for clean up expenses.

Sec. 22a-452a. State lien against real estate as security for amounts paid to clean up hazardous waste. (a) On and after June 3, 1985, any amount paid by the commissioner of environmental protection pursuant to subsection (b) of section 22a-451 to contain and remove or mitigate the effects of a spill shall be a lien against the real estate of the person causing such spill in accordance with the provisions of this section.

(b) A lien pursuant to this section shall not be effective unless (1) a certificate of lien is filed in the land records of each town in which the real estate is located, describing the real estate, the amount of the lien, the name of the owner as grantor and the name of the person causing the spill, if known, and (2) the commissioner mails a copy of the certificate to such persons and to all other persons of record holding an interest in such real estate over which the commissioner's lien is entitled to priority.

(c) Such lien shall take precedence over all transfers and encumbrances recorded on or after June 3, 1985, in any manner affecting such interest in such real estate or any part of it on which the spill occurred or from which the spill emanated, or real estate which has been included, within the preceding three years, in the property description of such real estate and is contiguous to such real estate. This subsection shall not apply to real estate which consists exclusively of residential real estate, including but not limited to, residential units in any common interest community, as defined in section 47-202.

(d) In the case of all other real estate, including real estate which consists exclusively of residential real estate, including but not limited to, residential units in any common interest community, as defined in section 47-202, the lien shall take precedence over any transfer or encumbrance recorded after the commissioner files with the town clerk notice of intent to file a lien on the land records in the town in which the real estate is located.

(e) When any amount with respect to which a lien has been recorded under the provisions of this section has been paid or reduced, the commissioner, upon request of any interested party, shall issue a certificate discharging or partially discharging such lien, which certificate may be recorded in the same office in which the lien was recorded. Any action for reduction or discharge of such lien or any appeal therefrom shall be in accordance with the provisions of sections 49-35a to 49-35c, inclusive, except that the forms prescribed in section 49-35a shall be modified as the court deems appropriate. Any action for the foreclosure of such lien shall be brought by the attorney general in the name of the state in the superior court for the judicial district in which the property subject to such lien is situated, or, if such property is located in two or more judicial districts, in the superior court for any one such judicial district, and the court may limit the time for redemption or order the sale of such property or make such other or further decree as it judges equitable.

(P.A. 84-535, S. 2; P.A. 85-443, S. 2, 5.)

History: P.A. 85-443 divided section into Subsecs. and amended Subsec. (a) to apply section to amounts paid after June 3, 1985, instead of October 1, 1984; inserted new provisions as Subsec. (b) to require filing of the lien in the town clerk's office; amended Subsec. (c) to give the lien precedence over transfers and encumbrances to property on which the spill occurred or emanated from three years prior to the spill except residential real estate; inserted new provisions as Subsec. (d) to give the lien precedence over all transfers after filing, and amended Subsec. (e) to authorize the commissioner to issue a certificate partially discharging the lien.

Sec. 22a-452b. Exemption. Notwithstanding any provision of the general statutes, a mortgagee who acquires title to real estate by virtue of a foreclosure or tender of a deed in lieu of foreclosure, shall not be liable for any assessment, fine or other costs imposed by the state for any spill upon such real estate beyond the value of such real estate, provided such spill occurred prior to the date of acquisition of title to such real estate by such mortgagee.

(P.A. 85-443, S. 3, 5.)

Sec. 22a-452c. Definition of spill. For the purposes of sections 22a-452a and 22a-452b, "spill" means the discharge, spillage, uncontrolled loss, seepage or filtration of oil or petroleum or chemical liquids or solid, liquid or gaseous products or hazardous waste.

(P.A. 85-443, S. 1, 5.)

Sec. 22a-453. (Formerly Sec. 25-54gg). Coordination of activities with other agencies. Contracts for services. The commissioner shall represent the state in its relations with the federal government and with any municipality and with any regional or interstate authority in all matters relating to oil or petroleum or chemical liquids or solid, liquid or gaseous products or hazardous wastes pollution or contamination or emergency resulting from the discharge, spillage, uncontrolled loss, seepage or filtration of such substance or material or waste. Said commissioner may enter into agreements with the federal government, such municipalities or authorities, to coordinate supervisory activities and, subject to adequate appropriations, share reasonable costs. The

STATE OF ALASKA
DEPARTMENT OF ENVIRONMENTAL CONSERVATION
OFFICE OF THE DEPUTY COMMISSIONER
JUNEAU

2/23

To Howard Wayne
c/o Rep. Sund's office

Here are the materials we have provided on HB 389 for House Resources: position paper
fiscal note
backup info from the AG's office.

Commissioner Niles and Dave Marty of the Dept. of Law will attend the hearing. We will be meeting with Rep. Sund tomorrow morning and can respond to any advance questions then.
Let me know if you need anything else. Amy

STATE OF ALASKA
DEPT. OF ENVIRONMENTAL CONSERVATION

STEVE COWPER, GOVERNOR

OFFICE OF THE COMMISSIONER
P.O. BOX O, JUNEAU, ALASKA 99811-1800 (907) 465-2600

April 8, 1988

Mr. John Hartle
c/o Rep. John Sund
PO Box V
Juneau, AK 99811

Dear John:

Here is the backup information you requested on CS HB 389 (Judiciary), the Governor's bill establishing a lien for oil and hazardous substances cleanup costs. We would be grateful if Representative Sund would be willing to serve as floor manager. The bill is before Finance today and could be scheduled as early as Tuesday.

The materials are:

1. Copy of the CS. This version gives the state a lien but not a priority lien for cleanup costs. This means that the state gets in line with secured creditors but does not have to first secure a judgement. The bill also strengthened notice requirements and clarified language.

2. Position paper on the CS.

3. Fiscal note.

4. Journal notes on Judiciary Committee action on the bill.

5. Minutes of House Resources Committee action on the bill.

6. Governor's transmittal letter for the bill.

7. Copy of Supreme Court decision recommending adoption of this kind of legislation.