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**Animal and
Plant Health
Inspection
Service**

Irradiation for Phytopsanitary Regulatory Treatment

**Environmental Assessment,
October 1997**

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I. Need for the Proposed Action

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), is proposing irradiation as a regulatory treatment method for phytosanitary certification of some agricultural commodities. This method could be used as an alternate treatment for importation and interstate movement of commodities (7 Code of Federal Regulations (CFR) Parts 300, 301, 318, and 319) or exportation of commodities (7 CFR Part 353). The proposed action incorporates this new treatment method as a component of the import, interstate movement, and export regulations for fruits and vegetables. Fruits and vegetables not currently cleared for import, interstate movement, or export from the United States could be certified based upon irradiation treatment.

Previous programs and documents have considered irradiation treatment only on a case-by-case basis for each facility or commodity use pattern (e.g., treatment of papayas from Hawaii (APHIS, 1988)). Unlike previous documents, this environmental assessment (EA) analyzes the potential environmental effects from the overall (programmatic) use of this treatment method for phytosanitary certification of fruits and vegetables.

Effective regulatory treatments approved for movement of these fruits and vegetables are limited. For example, one of the approved treatments (fumigation with methyl bromide) is being phased out gradually. Irradiation provides an alternative method for some of the commodities that are currently treated only by fumigation with methyl bromide. In this method-specific EA, APHIS analyzes the potential effects of the proposed program and limited no action alternative. The characteristics and issues that are unique to the irradiation process are considered in this assessment.

In accordance with the National Environmental Policy Act of 1969 (42 United States Code 4321–4347) (NEPA) and its implementing regulations, APHIS analyzed the potential environmental effects of import treatments required for phytosanitary certification in a programmatic EA, the “Proposed Rule for the Importation of Fruits and Vegetables—May 1995” (APHIS, 1995). The EA analyzed alternatives and control methods that could be used for importation of fruits and vegetables and included all regulatory treatment methods other than irradiation. The programmatic EA determined that the environmental risks related to these other treatment methods are inconsequential and concluded that future amendments of these treatments are categorically excluded. See 7 CFR § 372.5(c)(1) in 60 Fed. Reg. 6003 and 7 CFR § 372.5(d) in 60 Fed. Reg. 6004. All of the discussions, analyses, and conclusions of this EA are incorporated by reference.

II. Alternatives

A. Irradiation Treatment

This alternative provides agency programs with another regulatory treatment method for phytosanitary certification of fruits and vegetables for import, interstate movement, and export. The use of irradiation treatment does not replace the other available regulatory treatments, but provides another regulatory option. Under this alternative, the other treatments from the limited no action alternative would continue to be available and would continue to be used for regulatory purposes. The addition of irradiation regulatory treatments to the treatment schedule for fruits and vegetables could diminish the dependence on some of the other treatments. Although irradiation treatments have been found to effectively control many pests, the high cost of setting up an irradiation facility makes it likely that only a few larger facilities will actually seek certification from APHIS to use this technique. The use of irradiation treatment for phytosanitary purposes could expand with the anticipated increases in import and export of various fruits and vegetables resulting from the continuing development of new trade agreements.

The irradiation treatment involves exposure of the commodity, under controlled conditions, to gamma-rays (from Cobalt-60 or Cesium-137) or to electron beams (as produced by linear accelerators). The amount of energy absorbed (dose) is expressed in units of Grays. One Gray (100 rad) is equal to one joule absorbed per kg matter or 10,000 ergs absorbed per gram of matter. The total exposure of the treated commodity from regulatory treatments would vary from 250 to 1,000 Grays depending upon the commodity. The chemical changes to food from irradiation are similar to those from heat processing and are usually expressed in terms of the amount of substrate changed or new products formed.

B. Limited No Action

For the purposes of this proposed program, the limited no action alternative¹ is defined as continuation of the current program for phytosanitary treatments of agricultural commodities. This includes mandatory treatments of certain commodities for export, import, or interstate movement. The treatments include fumigation, heat treatments, steam treatments, hot water treatments, and cold treatments. For the program to be effective, it has to employ several treatment methods. The limited no action alternative affords the program a degree of flexibility to deal with pest risks over a broad spectrum of diverse commodities. Some fruits and vegetables have no approved quarantine treatments or have only one approved treatment. The limited treatment options allow only the movement of commodities from those locations that have adequate treatment

¹ A variety of interpretations may exist for the no action alternative, including entirely (no program) or possibly no Federal involvement. However, the most probable result of implementing either of these other interpretations would be that the existing high pesticide use patterns would continue. Under those circumstances, the environmental effects of no action would be more severe than those that might be incurred in the implementation of the proposed action. In APHIS' judgment therefore, the public's interest is better served through analysis of a limited no action alternative.

facilities. Lack of provision for irradiation treatment as an option for phytosanitary certification would be expected to result in increased restrictions on movement of those agricultural commodities that have few approved regulatory treatments and no movement of those commodities that only can be treated by irradiation.

III. Environmental Effects

The environmental impacts that may result from implementation of the proposed action and/or its alternatives are considered in this section. Because the principal environmental concern over this proposed program relates to human health issues over potential exposure to radiation and unique radiolytic products, this EA, therefore, focuses on the safety requirements of the facilities and potential effects of the radiolytic compounds that result from the treatments. It also considers the environmental effects from changes in or diminished use of other regulatory treatments.

A. Irradiation Treatment

1. Human Health

Consumption of irradiated fruits and vegetables poses no significant risk to consumers. The FDA issued a final rule regarding food irradiation in 1986 (21 CFR 179). Their proposed rule stated that the safety of food irradiation at doses below 1,000 Grays had been established because (1) irradiation will not make the food radioactive, (2) the chemical differences between irradiated food at these doses and nonirradiated food are too small to affect the safety of the foods, (3) the nutritional value of the food is not decreased at these irradiation doses, and (4) the balance between microbial spoilage organisms and pathogenic organisms is not adversely affected by these doses. Irradiation of food as a physical process is considered to be safer than other well-accepted techniques such as canning (Schubert, 1977). Much of the past controversy over the safety of irradiated food relates back to the chemicals formed by radiolysis. A joint expert committee (FAO/IAEA/WHO, 1977) determined that most of the radiolytic products were found at low concentrations (parts per billion) and most were also present in foods treated by conventional processes. The expert committee determined that the health hazard from these radiolytic products is negligible. The formation of free radicals and hydrogen peroxide in irradiated foods pose very low genetic risks. The genetic risk from consumption of irradiated food was found to be approximately 10,000 times lower than the natural probability of genetic error (Fernandez et al., 1984). Although irradiation treatments have been associated with off-flavors in some food, this has not been an issue of concern with fruits and vegetables.

An EA prepared by the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) determined that no adverse environmental effects are anticipated at food processing plants that are designed to irradiate fruits and vegetables (FDA, 1982). The Nuclear Regulatory Commission (NRC) has set stringent environmental protection requirements for any facilities that use radionuclide sources (10 CFR Parts 20, 30, 51, and 71). In addition, there are special carrier requirements for transport of hazardous materials (such as the radionuclides used at the facility) set by the U.S. Department of Transportation (DOT). Any extraneous radiation from radionuclides would be contained in plants by shielding required by the NRC and the

Bureau of Radiological Health at FDA. The source for the food irradiator is returned to the manufacturer for further use or disposal at the end of its useful life. The risk of radiation exposure to workers is very low with adherence to the required safety regulations. The irradiation facilities pose no routine risks to the general public, and public health concerns would occur only in the unlikely event of a major accident at the facility. Many safeguards prevent such incidents. Proper design and operating procedures of commercial irradiators have been shown to operate without significant radiation risk to workers or the public (CH2M Hill, 1987). APHIS ensures that the risks are insignificant by its requirement that all irradiation facilities adhere to the safety regulations of the NRC, DOT, and FDA.

Implementation of irradiation treatment as an alternative would mean that phytosanitary treatments of some regulated commodities could be achieved by irradiation. Availability of irradiation treatment could result in less need to use the other available treatment methods with all the resulting changes in potential impacts. The greatest potential environmental benefits would occur with the reductions in fumigations with methyl bromide. The resulting reduction of pesticide usage would diminish the potential for exposure to pesticide residues for both treatment personnel and consumers of treated fruits and vegetables. The possibility of indirect risks to humans resulting from ozone depletion alleged to be caused by methyl bromide in the atmosphere would decrease. Some work is still needed on developing effective and economical irradiation treatments for commodities that are now treated with methyl bromide; therefore, the availability of irradiation treatment to replace methyl bromide is limited to certain commodities.

Consistent with Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," APHIS considered the potential for disproportionately high and adverse human health or environmental effects on any minority populations and low-income populations. No evidence has been found to indicate that workers at the irradiation facilities or people consuming treated commodities would be adversely affected and that any adverse effects would be disproportionate to any minority or low-income populations. No disproportionate effects on such populations are anticipated as a consequence of implementing the preferred action.

2. Nontarget Species

No direct adverse effects are associated with the use of irradiation treatments. An indirect adverse effect could result if nontarget species entered the irradiation chambers during commodity treatments. This is unlikely based upon the design and safety features of the facilities. The consumption of irradiated food by nontarget species poses no significant risks to their health. Adherence to proper safety procedures required by the NRC, DOT, and FDA ensures that there will be no exposure of nontarget plant or animal life to radiolysis or radioactive particles.

The use of irradiation treatments could result in reductions of other treatment methods. Although methyl bromide exposure to nontarget organisms from regulatory treatments is already negligible, replacement of some methyl bromide treatments with irradiation treatment would further reduce the potential for exposure. The net effect on sensitive nontarget species (wildlife, livestock, and domestic animals and plants) would be a reduced risk of adverse effects from methyl bromide fumigations. The overall effect from the use of irradiation treatments, therefore, is regarded as positive.

The Endangered Species Act and its implementing regulations require Federal agencies to consult with the U.S. Department of the Interior's Fish and Wildlife Service and/or the U.S. Department of Commerce's National Marine Fisheries Service to ensure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat. APHIS has determined that, because of the contained and controlled nature of irradiation treatment, there is no potential to affect endangered or threatened species or their critical habitat.

3. Environmental Quality

The risks to environmental quality associated with irradiation treatments are negligible. Adherence to proper safety procedures required by the NRC, DOT, and FDA ensures that there will be no exposure of ambient air, water, or soil to radiolysis or radioactive particles.

B. Limited No Action

Continuation of the current regulatory treatments (maintenance of the status quo) would result in the same environmental effects that are occasionally noted. The EA for the proposed rule for the importation of fruits and vegetables (APHIS, 1995) found that the environmental risks from agency use of these treatments are inconsequential and indicated that future amendments to these regulatory treatments are categorically excluded. There are, however, some insignificant adverse impacts from these treatments. Potential adverse effects from methyl bromide and bromine residues would continue for some exposed humans and some nontarget species. Potential ozone depletion from methyl bromide fumigation would continue. Adverse effects could actually increase commensurate with increases in the demand for movement of the regulated commodities. The continuing impacts from current regulatory treatments exceed the negligible impacts anticipated from the addition of irradiation treatments as part of the phytosanitary regulations.

IV. Listing of Agencies, Organizations, and Individuals Consulted

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V. References Cited

APHIS—See U.S. Department of Agriculture, Animal and Plant Health Inspection Service.

CH2M Hill, 1987. Feasibility study for a commodities irradiation facility in the State of Hawaii (final report and attachments). State of Hawaii, April 1987.

FAO/IAEA/WHO—See Joint Food and Agriculture Organization/International Atomic Energy Agency/World Health Organization Expert Committee.

FDA—See U.S. Department of Health and Human Services, Food and Drug Administration.

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Schubert, J., 1977. Toxicological studies on irradiated food and food constituents. *In* Food preservation by irradiation, Vol. II. International Atomic Energy Agency, Vienna, Austria.

U.S. Department of Agriculture, Animal and Plant Health Inspection Service, 1995. Proposed rule for the importation of fruits and vegetables. Environmental Assessment, May 1995.

U.S. Department of Agriculture, Animal and Plant Health Inspection Service, 1988. Irradiation as a quarantine treatment for papaya. Finding of No Significant Impact, July 1988.

U.S. Department of Health and Human Services, Food and Drug Administration, 1982. Proposed regulation for the use of irradiation for the treatment of food. Environmental Assessment, September 1982.

**Finding of No Significant Impact
for
Irradiation for Phytosanitary Regulatory Treatment
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The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), has prepared an environmental assessment (EA) that analyzes potential environmental consequences of the inclusion of irradiation treatments for phytosanitary certification of fruits and vegetables. The EA, incorporated by reference in this document, is available from—

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The EA analyzed two alternatives—inclusion of irradiation as a phytosanitary treatment and limited no action. The limited no action is defined as continuation of the current program for phytosanitary treatments of agricultural commodities. Each of the alternatives has some potential environmental impacts, including limited no action, for which the environmental impacts would be those attributable to existing phytosanitary treatments. APHIS chose the irradiation treatment alternative because of its added capacity to treat infested agricultural commodities and its ability to reduce dependence on other treatments that produce pesticide residues that have potential adverse impacts.

I find that implementation of the irradiation treatments as a component of phytosanitary certification of fruits and vegetables for import, export, and interstate movement will not significantly impact the quality of the human environment. I have considered and based my finding of no significant impact on the previous documentation of phytosanitary treatments and on the operational characteristics of irradiation treatments. The potential of this program to reduce dependence on fumigation treatments with methyl bromide as a regulatory treatment makes this a desirable alternative.

In addition, APHIS anticipates no adverse impacts to threatened or endangered species or their habitats from this regulatory action. I find that the environmental process undertaken for this program is entirely consistent with the principles of “environmental justice,” as expressed in Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.”

Lastly, because I have not found evidence of significant environmental impact associated with the proposed changes in the phytosanitary treatments, I further find that an environmental impact statement does not need to be prepared and that proposed irradiation of fruits and vegetables may be employed as a regulatory phytosanitary treatment.

/s/

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Animal and Plant Health Inspection Service

October 6, 1997

Date