April 12, 2002

Regulatory Analysis and Development
PPD / APHIS
Station 3C71
4700 River Road - Unit 118
Riverdale, MD 20737-1238

Re: Docket No. 98-030-3 – "Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables"

To whom it may concern:

On behalf of our 150,000 members, Public Citizen has serious concerns about the above-referenced proposed USDA rule, which would permit the use of "irradiation treatment" on imported fruits and vegetables for the purpose of killing or sterilizing 11 species of fruit flies and one species of mango seed weevil.

Like APHIS, we are "aware of growing commercial interest in the use of irradiation as a treatment for agricultural products."[1] However, by incorporating irradiation into food production systems, major problems have been and are continuing to be overlooked.

I. The Proposed Rule is Premature and Subject to Challenge

In the Federal Register notice related to the proposed rule, the USDA stated that the agency has:

> decided that the monitoring section of the rule should allow APHIS to target its monitoring as needed and provide the appropriate level of monitoring, ranging from intermittent monitoring of operations and inspection of records to a continual APHIS presence at facilities and regular inspection of untreated and treated articles for target and nontarget pests.[2]

Accordingly, the USDA amended the proposed rule "to allow APHIS to provide an appropriate level of monitoring at irradiation facilities, depending on the situations in different countries." The USDA added the following provisions to the proposed rule:

> (f) *Monitoring and interagency agreements.* Treatment must be monitored by an inspector. This monitoring must include inspection of treatment records and unannounced inspections of the facility by an inspector, and may include inspection of articles prior to or after irradiation. Facilities that carry out irradiation treatment operations must notify the Director of Preclearance, PPQ, APHIS … of scheduled operations at least 30 days before operations commence, except where otherwise provided in the facility preclearance work plan. To ensure the appropriate level of monitoring, before articles may be imported in accordance with this section, the following agreements must be signed:
>
> (1) *Irradiation treatment framework equivalency work plan.* The plant protection service of a country from which articles are to be imported into the United States in accordance with this section must sign a framework equivalency work plan with APHIS. In this plan, both the foreign plant protection service and APHIS will specify the following items for their respective countries:
>
> (i) Citations for any requirements that apply to the importation of irradiated fruits and vegetables into that country;
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> (ii) The type and amount of inspection, monitoring, or other activities that will be required in connection with allowing the importation of irradiated fruits and vegetables into that country; and
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> (iii) Any other conditions that must be met to allow the importation of irradiated fruits and vegetables into that country.
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> (2) *Facility preclearance work plan.* Prior to commencing importation into the United States of articles treated at a foreign irradiation facility, APHIS and the plant protection service of the country from which articles are to be imported must jointly develop a preclearance work plan that details the activities that APHIS and the foreign plant protection service will carry out in connection with each irradiation facility to verify the facility's compliance with the requirements of this section. Typical activities to be described in this work plan may include frequency of visits to the facility by APHIS and foreign plant protection inspectors, methods for reviewing facility records, and methods for verifying that facilities are in compliance with the separation of articles, packaging, labeling, and other requirements of this section. This facility preclearance work plan will be reviewed and

> renewed by APHIS and the foreign plant protection service on an annual basis.
>
> (3) *Trust fund agreement.* Irradiated articles may be imported into the United States in accordance with this section only if the plant protection service of the country in which the irradiation facility is located has entered into a trust fund agreement with APHIS. That agreement requires the plant protection service to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing inspection and treatment monitoring services at the irradiation facility during that shipping season… The agreement will describe the general nature and scope of APHIS services provided at irradiation facilities covered by the
> agreement, such as whether APHIS inspectors will monitor operations continuously or intermittently, and will generally describe the extent of inspections APHIS will perform on articles prior to and after irradiation.

All of these provisions are premature and are subject to challenge, vis-à-vis pending revisions to the two main General Standards of the Codex Alimentarius Commission that relate to food irradiation.

Codex is currently considering a revision of its General Standard for Irradiated Foods. Under Section 2.3 of the proposed revision, "Facilities and Control of the Process," two provisions address issues raised in the USDA's proposed rule:

> 2.3.4 Control of the process within the facility should include the keeping of adequate records including quantitative dosimetry.
>
> 2.3.5 Premises and records should be open to inspection by appropriate authorities.

Codex is also currently considering a revision of its International Code of Practice for Radiation Processing of Food. The proposed revision contains two provisions that address issues raised in the USDA's proposed rule:

> 5.3.5 *Product and inventory control.* Incoming products should be logged and given a code number to identify the packages at each step in its path through the irradiation plant. All relevant parameters such as date, time, source strength, minimum and maximum dose, temperature, etc., should be logged against the code number of the product.
>
> 6.6 *Records of irradiation.* Radiation processors should maintain adequate records showing the food processed, identifying marks if packaged or, if not, the shipping details, the bulk density of the food,

> the dosimetry results, including the type of radiation source. All documentation should be available to authorized personnel and accessible for a period of time established by food control authorities.

Approval of neither of these proposed Codex revisions is imminent.

Although the proposed General Standard for Irradiated Foods is currently at Step 6 of the Codex's eight-step approval process, the proposal has been subject to an increasing level of opposition in recent months. Following concerns filed by the European Community, Germany and Poland, the Codex Committee on Food Additives and Contaminants (CCFAC) last month voted to delay further consideration of the proposal by one year. In order to become a new General Standard, the proposal must be approved by CCFAC, by all Codex member nations, and by the full Codex Commission.

Only last September was the proposed International Code of Practice for Radiation Processing of Food approved as "new work" by the Codex Executive Committee.

If and when these two proposals become new Codex General Standards, they will become the *de facto* standards of the World Trade Organization under the Agreement on the Application of Sanitary and Phytosanitary Measures. Any conflict between U.S. food standards and those of a WHO member nation could be challenged under the WTO's binding dispute resolution system.

In short, proceeding with the USDA's proposed rule would be premature and, accordingly, unwise.

II. The Potential Migration of Chemicals from Packaging Materials Has Not Been Assessed

In the Federal Register notice related to the proposed rule, the USDA stated that the agency has added the following provisions to the proposed rule:

> All fruits and vegetables treated with irradiation must be shipped in the same cartons in which they are treated… Each carton must bear an indicator device, securely attached prior to irradiation, that changes color or provides another clear visual change when it is exposed to radiation in the dose range required by this section for the pests for which the articles are being treated.

The USDA has not assessed:

(1) The chemicals that could be formed in irradiated packaging material;

(2) The potential that any of these chemicals could migrate into food; or

(3) The potential health hazards of any of these chemicals that could migrate into food.

The Food and Drug Administration, which has the primary responsibility to regulate irradiated foods, requires a safety assessment of proposed food additives, including additives derived from packaging material:

> [T]he following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.[3]

Implementing the proposed rule without a safety assessment of irradiated packaging material would put the USDA in non-compliance with the Federal Food, Drug, and Cosmetic Act.

III. Safer, Cleaner Alternatives Exist

Extensive evidence suggests that cold and hot treatment of perishables – not the use of radiation – is the least expensive technique to control pests in imports. Numerous studies have shown that cold and heat treatments, especially when combined with basic sanitation methods, can meet the mandated control level of probit 9 for fly control.

In cold treatments, the fruit is cooled to 0° and held at that temperature for 13-16 days without noticeable changes to the quality of the fruit. While cold treatment is energy intensive, it is not as expensive as heat treatment. And, it does not approach the costs related to irradiation.

The U.S. Environmental Protection Agency states in its "Methyl Bromide Alternative Case Study" of 1997 that cold treatment is:

> "effective against insect pests and pathogens (Carpenter and Potter 1994) and has the added benefit of improving the quality of grapes and extending their shelf life by lowering respiration rates (Mitcham et al. 1994). Other benefits include the prevention of color change and softening and the maintenance of fruit composition and nutritional value. Furthermore, the gas used in this technology are chemically inert and will not corrode handling equipment (Ke and Kader 1992, Calderon and Barkai-Golan 1990). Unlike some other fumigants, controlled atmosphere treatments (with carbon dioxide and/or nitrogen) do not leave toxic residues on grapes. The treatment also penetrates more easily than most fumigants because of its small molecular size (Smith and Newton 1992). Furthermore, grapes are ideally suited for this treatment technique because they produce very little ethylene (a compound emitted from fruit which stimulates ripening) and are highly resistant to its effects (Lamb 1996)."[4]

Unfortunately, heat treatments are harder to apply and can damage the commodity being treated. However, USDA should provide support to those wishing to use this alternative.

The use of controlled atmospheres, which elevates the amount of carbon dioxide or reduces the oxygen content of the air in a shipping container, has been a viable alternative to methyl bromide for 10 or more years.

Each of these treatments – when combined with basic phytosanitary procedures such as keeping facilities impeccably clean and limiting exposure to the outside except when conducting infestation surveys – are highly effective.

IV. Radiation Has Mutagenic Properties

In November 1926, Hermann Joseph Muller discovered that x-rays cause mutations in *Drosophila melanogaster* (fruit flies) – a discovery for which Muller earned the Nobel Prize in Medicine.

Since the work of Muller, scientists throughout the world have conducted hundreds of studies into the mutagenicity of radiation. Over the past seven decades, the findings of Muller have been confirmed time and time again.

Much of the research into the mutagenic effects of radiation on fruit flies was conducted by a protégé of Muller, Robert Rinehart. During his 33-year-career, Rinehart worked as a genetics researcher at the Oak Ridge National Laboratory (under a fellowship from the U.S. Public Health Service) and taught biology at San Diego State University, where much of his genetics research was underwritten by the U.S. Atomic Energy Commission.

In two of the many studies he conducted during the 1960 and 1970s, Rinehart grew *Drosophila melanogaster* on irradiated food. The studies revealed that irradiated food caused a significantly higher mortality rate and spawned up to 157 percent more mutations than food that had not been exposed to radiation.[5, 6]

Among the other studies that have explored the mutagenic effects of irradiation on fruit flies:

- Sex-linked recessive lethal mutations appeared 3-4 times more frequently in *Drosophila melanogaster* grown in irradiated medium.[7]

- Sex-linked recessive lethal mutations appeared 2.5 times more frequently in *Drosophila melanogaster* grown in irradiated medium.[8]

- A 33-fold increase in sex-linked recessive mutations appeared in *Drosophila melanogaster* following the addition of irradiated DNA.[9]

• Up to a 133 percent increase in sex-linked recessive mutations appeared in *Drosophila melanogaster* grown in irradiated medium and/or to which irradiated DNA was added.[10]

Given the inherent randomness of genetic mutations, allowing imported fruits and vegetables – or *any* fruits and vegetables, for that matter – to be "treated" with irradiation would be irresponsible. Nothing is known about the prospective behavior of any prospective mutant forms of fruit flies and mango seed weevils. No one can predict how these organisms could mutate when exposed to radiation or how any mutant forms could be eradicated.

Concerns throughout the scientific community about the growing problem of mutant bacteria, viruses and other lifeforms are on the rise. The World Health Organization announced last month that humans are losing the war against bacteria and viruses: "We literally are in a race against time to bring levels of infectious disease down worldwide, before diseases wear drugs down first. Currently, there are no new drugs or vaccines ready to quickly emerge from the research and development pipeline."[11]

The USDA states that, if the proposed regulations go into effect, it is anticipated that 32 fertile fruit flies or mango seed weevils per million could survive irradiation "treatment" at the recommended doses.[12] Any organism that survives an exposure to radiation stands the chance of mutating – perhaps into a form that is more resistant to radiation or any other "treatment."

V. Food is Depleted of Nutrients

Virtually all types of food – including fruits and vegetables – suffer nutrient destruction and loss of quality when exposed to radiation. In many cases, even small doses of radiation can result in significant loss of vitamins and other nutrients, and a significant decline of food quality.

For example:

• Potatoes irradiated at 0.1 kGy suffered a loss of beta-carotene of up to 50 percent.[13]

• The vitamins that are most sensitive to radiation are A, B_1 (thiamin) C and E. Among the main sources of beta-carotene (a component of vitamin A) is green and red vegetables, and yellow and red fruits. Among the main sources of vitamin B_1 is beans. The main source of vitamin C is fruits and vegetables.[14]

VI. Conclusion

Public Citizen requests that the USDA withdraw this proposed rule pertaining to the "Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables." This rule holds the potential to vastly expand food imports into the U.S. This is a dangerous prospect.

Until the irradiation of food can be demonstrated as being safe, this technology should not be used to "treat" imported fruits and vegetables – or any other food, for that matter. Dozens of studies performed over the past 50 years – many of them funded or conducted by the U.S. government – have shown that irradiated food is unwholesome and unsafe.

For example:

- Irradiated food has caused myriad health problems in laboratory animals (and people in one study), including premature death, fatal internal bleeding, stillbirths and other reproductive problems, genetic damage, a rare form of cancer, organ damage, and nutritional deficiencies.

- Irradiation can result in the formation of chemicals known or suspected to cause cancer and birth defects, including benzene, toluene and methyl ethyl ketone.

- Irradiation can result in the formation of cyclobutanones, a group of chemicals recently were shown to promote the carcinogenic process, and to cause genetic and/or cellular damage in rats, and in human and rat cells.

- Irradiation can result in the formation of dozens and perhaps hundreds of unique radiolytic products that have not been adequately identified or studied for their potential harm to humans.

- Irradiation can spawn mutant forms of *E. coli*, *Salmonella* and other harmful bacteria, potentially making them more difficult to sterilize or kill.

- Irradiation can kill beneficial microorganisms, such as the yeasts and molds that help keep botulism at bay, as well as the microorganisms that create the aromas that tell us when food has gone bad.

We appreciate the opportunity to comment on this important matter, which is of great concern to American consumers.

Respectfully submitted,

Wenonah Hauter
Director, Critical Mass Energy and Environment Program

References

[1] 65 FR 34113 (May 26, 2000).

[2] 67 FR 11610 (March 15, 2002).

[3] 21 CFR §170.22

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[5] Rinehart, R.R. and Ratty, F.J. "Mutation in *Drosophila Melanogaster* Cultured on Irradiated Food." *Genetics*, 52:1119-1126 (1965).

[6] Rinehart, R.R. and Ratty, F.J. "Mutation in *Drosophila Melanogaster* Cultured on Irradiated Whole Food or Food Components." *International Journal of Radiation Biology*, 12:347-354 (1967).

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[9] Parkash, Om. "Induction of sex-linked recessive lethals and visible mutations by X-irradiated DNA in *Drosophila melanogaster." Nature*, 205:312-313 (1965).

[10] Chopra, V.L. "Tests on *Drosophila* for the production of mutations by irradiated medium and irradiated DNA." *Nature*, 208:699-700 (1965).

[11] Kaufman, Marc. "Microbes Winning War." *Washington Post*, June 13, 2000, p A1.

[12] 65 FR 34114 (May 26, 2000).

[13] Data of Janave and Thomas (1979), cited in Kilcast, D. "Effect of irradiation on vitamins." *Food Chemistry*, 49:157-164 (1994).

[14] Janane and Thomas (1979).