

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 99F-1912]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DMB

Display Date	11/28/00
Publication Date	11/29/00
Certifier	Monica Givner

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ultraviolet (UV) irradiation to reduce human pathogens and other microorganisms in juice products. This action is in response to a food additive petition filed by California Day-Fresh Foods, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3088.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 25, 1999 (64 FR 34258), FDA announced that a food additive petition (FAP 9M4676) had been filed by California Day-Fresh

Foods, Inc., 533 West Foothill Blvd., Glendora, CA 91741. The petitioner proposed that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of UV light to reduce human pathogens and other microorganisms in juice products.

II. Safety Evaluation

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. The additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction of human pathogens and other microorganisms in juice products.

A. Toxicology

FDA has evaluated the safety of the use of UV irradiation to reduce human pathogens and other microorganisms in juices. This safety assessment was based on the current understanding of the effects of UV irradiation on the major chemical components of food. Having evaluated the data in the petition and other relevant material in the agency's files, the agency finds that any photochemical changes that may occur as a result of the UV irradiation are of no toxicological significance (Ref. 1).

B. Microbiology

The petitioner submitted data demonstrating the reduction of specific pathogens (*Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*) inoculated into four types of juices (orange, apple, carrot, and garden vegetable). These four juice varieties are representative of the types of juice that are consumed by the U.S. population and that could be treated with UV irradiation (Ref. 2). After UV irradiation, there were significant reductions in pathogens. FDA concludes that the proposed use is effective in reducing human pathogens in juices and that treated juices will be

at least as safe as untreated juices currently on the market (Ref. 3). However, the submitted microbiological data do not constitute the type of validation studies necessary to demonstrate the achievement of specific performance standards, e.g. 5-log reductions, for human pathogen control programs (Ref. 3). Therefore, users of this UV treatment who are subject to certain performance standards will need to establish that this treatment meets their required level of human pathogen reduction.

C. Specifications for Use

The petitioned UV radiation is produced by low pressure mercury lamps, which emit more than 90 percent of their light at 253.7 nanometers (nm) (2,537 Angstroms); juice being treated passes through a transparent tube in which the juice is subjected to UV irradiation. Because most juices strongly absorb UV radiation, most of the UV radiation would be absorbed by the juice at the wall of the tube near the source of the UV irradiation. However, the amount of UV irradiation that would reach juice in the middle of the tube would be insufficient to reduce significantly human pathogens. Therefore, the petitioner proposed that the juices flow under turbulent conditions that produce eddies and swirls in the juice to ensure that as much juice as possible will reach the wall of the UV transparent tube where the juice would be exposed to UV irradiation. This would help to reduce human pathogens and other microorganisms throughout the juice. The conditions for turbulent flow are described mathematically by the unitless Reynolds number (Re):

[INSERT ILLUSTRATION]

where:

D is the tube diameter,

u is fluid velocity,

p is fluid density, and

μ is fluid viscosity.

3a

$$Re = \frac{Dup}{\mu}$$

To ensure that sufficient turbulent flow is achieved, the petitioner has requested that a limit of a Reynolds number of no less than 2,200 be incorporated into the regulation. FDA concurs with this specification (Ref. 4).

The amount of UV irradiation necessary for human pathogen reduction will depend on various factors, such as the type of juice, the initial microbial load, and the design of the irradiation system (e.g., flow rate, number of lamps, and time exposed to irradiation). Therefore, FDA is not specifying a minimum or maximum dose by regulation, but concludes that this should be achieved for individual usage situations in a manner consistent with good manufacturing practice (Ref. 5). FDA expects that the maximum dose applied to the juice will be economically self-limiting due to the costs associated with UV irradiation. Additionally, the levels of UV irradiation applied to the juice will be limited by the possible alterations in organoleptic characteristics of the juice (i.e., changes in taste or color) after UV irradiation, changes that may result in decreased consumer acceptance. Thus, juice processors will also limit the maximum applied dose of UV irradiation to avoid production of a product not acceptable to consumers (Ref. 5).

Based on the data and studies submitted in the petition and other information in the agency's files, FDA concludes that the proposed use of UV irradiation of juice products is safe, that the irradiation will achieve its intended technical effect, and therefore, that the regulations in § 179.39 should be amended as set forth below.

D. Other Changes to § 179.39

FDA is also making an editorial change to the existing regulation to describe more accurately the approved emission sources and to remove an unnecessary and confusing description. This change does not affect the nature or properties of permitted sources. Currently, § 179.39(a) stipulates that "The radiation sources consist of ultraviolet emission tubes designed to emit wavelengths within the range of 2200–3000 Angstrom units with 90 percent of the emission being the wavelength 2537 Angstrom units." The stipulation that 90 percent of the emission is at 253.7 nm (2,537 Angstroms) is sufficient to describe the sources as low pressure mercury lamps.

Furthermore, since a small percentage of the emission from these tubes is outside of the 220.0 to 300.0 nm (2,200 to 3,000 Angstroms) range, this restriction is factually inaccurate. Therefore, FDA is removing the restriction of the wavelength range in § 179.39(a) and in the table in paragraph (b) under the "Limitations column," and is instead specifying that the source of the irradiation to be low pressure mercury lamps.

III. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the Filing Notice for FAP 9M4676 (June 25, 1999, 64 FR 34258). 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.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by *[insert date 30 days after date*

of publication in the Federal Register]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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 are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA Memorandum, A. Mattia to W. Trotter, November 2, 1999.
2. FDA Memorandum, E. Jensen to W. Trotter, September 6, 2000.
3. FDA Memorandum, R. Merker to W. Trotter, January 26, 2000.
4. FDA Memorandum, E. Jensen to W. Trotter, October 27, 1999.
5. FDA Memorandum, E. Jensen to W. Trotter, October 27, 2000.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR 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 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

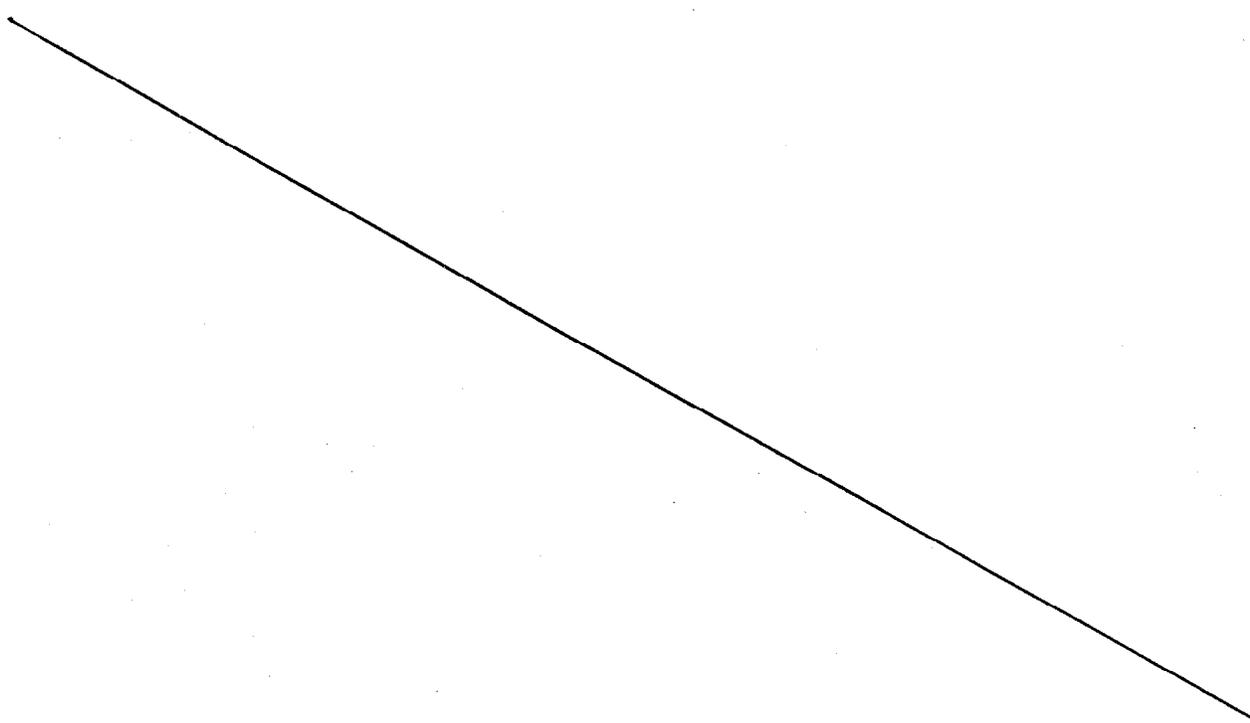
2. Section 179.39 is amended by revising paragraph (a) and by revising the table in paragraph (b) to read as follows:

§ 179.39 Ultraviolet radiation for the processing and treatment of food.

* * * * *

(a) The radiation sources consist of low pressure mercury lamps emitting 90 percent of the emission at a wavelength of 253.7 nanometers (2,537 Angstroms).

(b) * * *



Irradiated food	Limitations	Use
Food and food products	Without ozone production: high fat-content food irradiated in vacuum or in an inert atmosphere; intensity of radiation, 1 W (of 2,537 A. radiation) per 5 to 10 ft. ²	Surface microorganism control.
Potable water	Without ozone production; coefficient of absorption, 0.19 per cm or less; flow rate, 100 gal/h per watt of 2,537 A. radiation; water depth, 1 cm or less; lamp-operating temperature, 36 to 46 °C.	Sterilization of water used in food production.
Juice products	Turbulent flow through tubes with a minimum Reynolds number of 2,200.	Reduction of human pathogens and other microorganisms.

Dated: 11/14/00
November 14, 2000

L. Robert Lake

L. Robert Lake
Director of Regulations and Policy
Center for Food Safety and Applied Nutrition

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Wanda Oliver