

5. In § 55.45, paragraph (b) is revised to read as follows:

**§ 55.45 Operating tests.**

\* \* \* \* \*

(b) *Implementation*— (1) *Administration.* The operating test will be administered in a plant walkthrough and in either—

(i) A simulation facility which the Commission has approved for use after application has been made by the facility licensee; or

(ii) A plant-referenced simulator as defined in § 55.4.

(2) *Commission-approved simulation facilities.* (i) Facility licensees who propose to use a simulation facility in the administration of the operating test in accordance with paragraph (b)(1)(i) of this section, shall submit an application for approval of the simulation facility to the Commission. This application must include:

(A) A description of the components of the simulation facility that are intended to be used for each part of the operating test, unless previously approved;

(B) A description of the performance tests as part of the application, and the results of these tests; and

(C) A description of the procedures for maintaining examination and test integrity consistent with the requirements of § 55.49.

(ii) The Commission will approve a simulation facility if it finds that the simulation facility and its proposed use are suitable for the conduct of operating tests for the facility licensee's reference plant under paragraph (a) of this section.

(3) *Plant-referenced simulators.* (i) Facility licensees which propose to use a plant-referenced simulator to meet the experience requirements in § 55.31(a)(5) must ensure that:

(A) The plant-referenced simulator uses models relating to nuclear and thermal-hydraulic characteristics that replicate the core load that exists in the nuclear power unit for which a license is being sought at the time of the applicant's operating test; and

(B) Simulator fidelity has been demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(ii) If the Commission determines that a simulation facility consisting solely of a plant-referenced simulator does not meet either the definition of a plant-referenced simulator as defined in § 55.4, or the criteria in § 55.45(b)(4)(A) and (D), the Commission will not accept

the plant-referenced simulator for conducting operating tests as described in § 55.45(b)(1) of this part, requalification training as described in § 55.59(c)(3) of this part, or performing control manipulations that affect reactivity to establish eligibility for an operator's license as described in § 55.31(a)(5).

(4) *Continued assurance of simulator fidelity.* Facility licensees that maintain a simulation facility shall:

(A) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to assure that the criteria of paragraphs 55.45(b)(4)(C) and 55.45(b)(3)(i)(B) as applicable, are met. The results of performance tests must be retained for four years after the completion of each performance test or until superseded by updated test results;

(B) Correct scenario validation, performance test, modeling, and hardware discrepancies;

(C) Make available for NRC review, before or concurrent with preparations for each operator licensing operating test or requalification program inspection, results of any uncorrected performance test failures that may exist at the time of the operating test or requalification program inspection; and

(D) Maintain the provisions for examination and test integrity consistent with § 55.49.

\* \* \* \* \*

6. In § 55.59, paragraph (c)(4)(iv) is revised to read as follows:

**§ 55.59 Requalification.**

\* \* \* \* \*

(c) \* \* \*

(4) \* \* \*

(iv) Simulation of emergency or abnormal conditions that may be accomplished by using the control panel of the facility involved or by using a simulator. Where the control panel of the facility is used for simulation, the actions taken or to be taken for the emergency or abnormal condition must be discussed; actual manipulation of the plant controls is not required. If a simulator is used in meeting the requirements of paragraph (c)(4)(iii) of this section, it must accurately reproduce the operating characteristics of the facility involved and the arrangement of the instrumentation and controls of the simulator must closely parallel that of the facility involved. After the provisions of § 55.45(b) have been implemented at a facility, the simulation facility must be used to comply with this paragraph.

\* \* \* \* \*

Dated at Rockville, Maryland, this 27th day of June, 2000.

For the Nuclear Regulatory Commission.

**Annette L. Vietti-Cook,**

*Secretary of the Commission.*

[FR Doc. 00-16751 Filed 6-30-00; 8:45 am]

**BILLING CODE 7590-01-U**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

[Docket No. 00N-1351]

**Food Labeling; Use of the Term "Fresh" for Foods Processed With Alternative Nonthermal Technologies; Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Announcement of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to discuss the use of the term "fresh" in the labeling of foods processed with alternative nonthermal technologies. The purpose of the meeting is to determine whether the use of the term "fresh" is truthful and not misleading on foods processed with these alternative technologies and to determine what type of criteria FDA should use when considering the use of the term with future technologies.

**DATES:** The public meeting will be held on July 21, 2000, from 8:30 a.m. to 4 p.m. Please preregister by July 14, 2000. Late registrations will be accepted contingent on space availability. Comments must be submitted no later than August 21, 2000.

**ADDRESSES:** The meeting will be held at the Holiday Inn City Centre, 300 East Ohio St., Chicago, IL, 312-787-6100.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address: [FDADockets@oc.fda.gov](mailto:FDADockets@oc.fda.gov) or on the FDA website at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>.

**FOR FURTHER INFORMATION CONTACT:**

For registration: Kimberly Phillips or Darlene M. Bailey, Office of Public Affairs (HFR-CE645), Food and Drug Administration, 300 South Riverside Plaza, suite 550 South, Chicago, IL 60606, 312-353-7126 or FAX 312-886-3280.

For general information: Geraldine A. June, Center for Food Safety and Nutrition, Food and Drug Administration (HFS-822), 200 C St. SW., Washington, DC 20204, 202-205-4168 or FAX 202-205-5295.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of January 6, 1993 (58 FR 2302 at 2401), FDA published a final rule that established labeling regulations that govern the use of the terms "fresh," "freshly \_\_\_\_\_" (e.g., "freshly baked") and "fresh frozen" as they appear on the labeling of foods, including the use of these terms in brand names and as sensory modifiers. As discussed in the final rule, we issued this regulation because of the continued misuse of the term "fresh" and related terms in the marketplace.

We concluded at that time that it was necessary to establish a definition for "fresh" to preclude the type of misuse that we encountered most often, i.e., use of the term to imply that a food is unprocessed, when in fact it has been processed. Thus, provisions in § 101.95 (21 CFR 101.95) govern the use of the term "fresh" when used on the labels or in labeling of foods to suggest or imply that the food is unprocessed. Generally, the appearance of the term "fresh" on a label or in labeling means that the food in its raw state or finished form has not been frozen or subjected to any form of thermal processing or any other form of preservation. However, we provided that the following treatments do not preclude the food from bearing the term "fresh": (1) The addition of approved waxes or coatings, (2) the post-harvest use of approved pesticides, (3) the application of a mild chlorine wash or mild acid wash on produce, or (4) the treatment of raw foods with ionizing radiation not to exceed the maximum dose of 1 kiloGray.

The regulation also notes that use of the term "fresh" is not precluded when it does not imply that the food is unprocessed, e.g., "fresh" may be used to describe pasteurized whole milk because consumers understand that almost all milk is pasteurized and, therefore, there is no misleading implication.

Recently, manufacturers have developed new alternative food processing technologies to control pathogens in foods while minimizing the thermal component of the process. Such processes include, but are not limited to, high pressure processing, pulsed electric field, pulsed light, submerged arc, and filtration.

FDA contracted with the Institute of Food Technologists (IFT) to review and evaluate the scientific information available on these new alternative technologies and to assist us in evaluating each technology's effectiveness in reducing and inactivating pathogens of public health concern. Where information on these technologies was too limited for a thorough evaluation and conclusion, IFT identified research needs. The final report of this work, entitled "Kinetics of Microbial Inactivation for Alternative Food Processing Technologies" (Ref. 1), is available on FDA's website at [www.cfsan.fda.gov](http://www.cfsan.fda.gov).

Manufacturers using these processes contend that their products maintain the same "fresh" characteristics as unprocessed products. Thus, these manufacturers have asked FDA if they may label these products with the term "fresh." We are interested in obtaining the views of interested parties on the use of the term "fresh" for foods processed with these technologies. Thus, we have decided to hold a public meeting to engage interested parties in discussion on this issue. We will use information gathered at this meeting, as well as other information available to FDA, in considering whether to initiate rulemaking to amend § 101.95.

In this notice, we are announcing a public meeting to discuss the use of the term "fresh" in the labeling of foods processed with the alternative technologies. We are soliciting public comment on whether the use of the term "fresh" is truthful and not misleading on foods processed with these alternative technologies and on what type of criteria FDA should use when considering the use of the term with future technologies. Specifically, we invite comment on the following questions:

1. Do consumers associate the term "fresh" with organoleptic characteristics, nutritional characteristics, or some other characteristics?
2. Do consumers want a way to identify foods that taste and look fresh but have been processed to control pathogens?
3. What does industry think the term "fresh" means?
4. Is the term "fresh" when applied to foods processed with the new technologies misleading to consumers?
5. Do the new technologies preserve the foods?
6. Are the new technologies truly nonthermal?
7. Are there quantifiable parameters, e.g., level of nutrients, vitamins etc.,

that could be measured to determine if a food is "fresh?"

8. Is there a term other than "fresh" that can be used for foods processed with the new technologies?

9. Would consumers understand a new term?

10. What is the economic impact of allowing use of the term "fresh" for foods processed with the new technologies?

11. Would allowing the term "fresh" on foods processed with new technologies place small firms not able to use these technologies at an economic disadvantage?

At the public meeting, we will be addressing whether the use of alternative processing technologies should preclude the use of the term "fresh." Therefore, the public meeting will be restricted to the discussion of whether these processes fit the criteria for the use of the term "fresh" and not whether other aspects of the provisions in § 101.95 should be reopened.

##### II. Registration and Requests to Make Oral Presentations

If you would like to attend the meeting, you must preregister in writing with the contact person for registration (address above) by July 14, 2000, by providing your name, title, business affiliation, address, telephone and fax number. Preregistered persons should check in before the meeting between 8 a.m. and 8:30 a.m. Persons who have not preregistered may register before the meeting between 8 a.m. and 8:30 a.m., dependent on space availability. To expedite processing, this registration information also may be sent to the contact person by FAX to 312-886-3280. If you need special accommodations due to disability (e.g., sign language interpreter), please inform the contact person when you register.

If, in addition to attending, you wish to make an oral presentation during the meeting, you must so inform the contact person and submit: (1) A brief written statement of the general nature of the views you wish to present and (2) the names and addresses of the persons who will give the presentation. Depending on the number of people who register to make presentations, we will limit the time allotted for each presentation. We anticipate that, if time permits, those attending the meeting will have the opportunity to ask questions during the meeting.

##### III. Comments

Interested persons may, on or before August 21, 2000, submit written comments to the Dockets Management Branch (address above). You may also

send comments to the Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or to the FDA website at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. Please address your comments to the docket number given at the beginning of this notice. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

#### IV. Transcripts

You may request a transcript of the meeting from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after August 11, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA website at <http://www.fda.gov>.

#### V. Reference

We have placed the following reference on display in the Dockets Management Branch. You may see it at that office between 9 a.m. and 4 p.m., Monday through Friday.

1. Institute of Food Technologists, "Kinetics of Microbial Inactivation for Alternative Food Processing Technologies," A report of the Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services, June 2, 2000.

#### REGISTRATION FORM

Public Meeting on Use of the Term "Fresh" on Foods Processed with Alternative Nonthermal Technologies

Instructions: To register, complete this form and mail it to the address of the contact person(s) for registration or fax it to 312-886-3280 by July 14, 2000.

Name, \_\_\_\_\_  
 Title, \_\_\_\_\_  
 Company, \_\_\_\_\_  
 Address, \_\_\_\_\_  
 Telephone, \_\_\_\_\_  
 Fax, \_\_\_\_\_  
 E-mail, \_\_\_\_\_

Please indicate the type of organization that you represent:

Industry \_\_\_\_\_  
 Government \_\_\_\_\_  
 Consumer Organization \_\_\_\_\_  
 Media \_\_\_\_\_  
 Law Firm \_\_\_\_\_  
 Educational Organization \_\_\_\_\_  
 Other (specify) \_\_\_\_\_

Do you wish to make an oral presentation?

Yes \_\_\_\_\_

No \_\_\_\_\_

If yes, you must also submit the following:

1. A brief statement of the general nature of the views you wish to present,
2. The names and addresses of all persons who will participate in the presentation, and depending on the number of people who register to make presentations, we will limit the time allotted for each presentation.

Dated: June 27, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00-16716 Filed 6-28-00; 1:38 pm]

**BILLING CODE 4160-01-F**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 141 and 142

[FRL-6728-2]

#### Announcement of Stakeholders Meeting on Arsenic in Drinking Water Proposed Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of stakeholders meeting.

**SUMMARY:** The Environmental Protection Agency (EPA) will be holding a one-day Stakeholders meeting on August 9, 2000 in Reno, Nevada. The purpose of this meeting is to present information and to answer questions on the proposed rule. EPA is encouraging people to attend from State and Tribal drinking water programs, the regulated community (water systems), public health organizations, academia, environmental and public interest groups, engineering firms, and other interested stakeholders.

**DATES:** The stakeholder meeting on arsenic in drinking water will be held on Wednesday, August 9, 2000 from 8 a.m. to 12 pm and 1 p.m. to 5 p.m. PDT.

**ADDRESSES:** The meeting will be held at the Reno Hilton [(800) 648-5080], which is located at 2500 E. Second Street, Reno, NV 89595.

To register for the meeting, please contact the Safe Drinking Water Hotline at 1-800-426-4791 between 9 am and 5:30 p.m. EST. Those registered for the meeting by Friday, July 28, 2000 will receive an agenda, logistics sheet, and a copy of the **Federal Register** notice prior to the meeting. There will be a limited number of conference lines available. These lines will be allocated on a first-come, first-served basis. Members of the public who cannot attend the

meeting in person should register with the Safe Drinking Water Hotline by July 28 to receive copies of the overheads in advance. Please provide your name, organization, title, mailing address, telephone number, facsimile number, e-mail address and telephone number for EPA to connect the caller via conference call [if applicable] for the "Arsenic Meeting."

**FOR FURTHER INFORMATION CONTACT:** For general information on meeting logistics, please contact the Safe Drinking Water Hotline at 1-800-426-4791. For information on the activities related to the proposed arsenic rule, contact the Safe Drinking Water Hotline at 1-800-426-4791, or visit the EPA Office of Ground Water and Drinking Water arsenic webpage at <http://www.epa.gov/OGWDW/ars/arsenic.html>, which contains electronic copies of two fact sheets, the proposed rule, and the discussion papers and executive meeting summaries from previous stakeholders meetings. Registrants must make their own room reservations for the Reno Hilton by July 7, 2000 by calling (800) 648-5080 and mention "EPA Arsenic in Drinking Water Meeting" to guarantee the room rate of \$55 plus tax.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

Arsenic (As) is a naturally occurring element found in the human body and is present in food, water, and air. Arsenic in drinking water occurs in ground water and surface water and is associated with certain natural geologic conditions, as well as with contamination from human activities. Arsenic ingestion is linked to skin cancer and arsenic inhalation to lung cancer. In addition, arsenic ingestion seems to be associated with vascular effects, gastrointestinal irritation, and cancers of the kidney, bladder, liver, lung, and other organs. Water primarily contains inorganic arsenic species (As<sup>V+</sup> and As<sup>III+</sup>).

On August 6, 1996, Congress amended the SDWA, adding section 1412(b)(12)(A) which requires, in part, that EPA propose a NPDWR for arsenic by January 1, 2000 and issue a final regulation by January 1, 2001. The current maximum contaminant level (MCL) of 50 µg/L remains in effect until the effective date of the revised rule.

The National Primary Drinking Water regulation for arsenic proposes a Maximum Contaminant Level Goal (MCLG) of zero, an MCL of 5 µg/L, and lists best available technologies and small system compliance technologies. In addition, the proposed rule,