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#### North Mariana Islands

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#### Virgin Islands

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Please direct all questions and correspondence about intergovernmental review to:

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If you would like a copy of this list faxed to your office, please call our publications office at: (202) 395-9068

\* In accordance with Executive Order #12372, "Intergovernmental Review of Federal Programs," this listing represents the designated State Single Points of Contact. The jurisdictions not listed no longer participate in the process BUT GRANT APPLICANTS ARE STILL ELIGIBLE TO APPLY FOR THE GRANT EVEN IF YOUR STATE, TERRITORY COMMONWEALTH, ETC DOES NOT HAVE A "STATE SINGLE POINT OF CONTACT." STATES WITHOUT "STATE SINGLE POINTS OF CONTACT" INCLUDE: Alabama, Alaska; American Samoa; Colorado; Connecticut; Kansas; Hawaii; Idaho; Louisiana; Massachusetts, Palau; Minnesota; Montana; Nebraska; New Jersey; Oklahoma; Oregon; Pennsylvania; South Dakota; Tennessee; Vermont, Virginia; and Washington. This list is based on the most current information provided by the States. Information on any changes or apparent errors should be provided to the Office of Management and Budget and the State in question. Changes to the list will only be made upon formal notification by the State. Also, this listing is published biannually in the Catalogue of Federal Domestic Assistance.

#### Certification Regarding Environmental Tobacco Smoke

Public Law 103-227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the

imposition of a civil monetary penalty of up to \$1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

#### Attachment H, DHHS Regulations Applicable to Grants

The following DHHS regulations apply to all applicants/grantees under the Training and Technical Assistance Program

Title 45 of the *Code of Federal Regulations*:

Part 16—Procedures of the Departmental Grant Appeals Board

Part 74—Administration of Grants (non-governmental)

Part 74—Administration of Grants (State and local governments and Indian Tribal affiliates):

#### Sections

- 74.26 Non-Federal Audits
- 74.27 Allowable Costs for Hospitals and Other Non-profit Organizations
- 74.90 Final Decisions in Disputes
- 74.32 Real Property
- 74.34 Equipment and
- 74.35 Supplies
- 74.24 General Program Income

Part 74—20-28 Fiscal Management

Part 74—40-48 Procedure Standards

Part 74—50-53 Reports and Records

Part 75—Informal Grant Appeal Procedures

Part 76—Debarment and Suspension form Eligibility for Financial Assistance

#### Subpart—Drug Free Workplace Requirements

Part 80—Non-discrimination

Under Programs Receiving Federal Assistance through the Department of Health and Human Services

Effectuation of Title VI of the Civil Rights Act of 1964

Part 81—Practice and Procedures for Hearings Under Part 80 of this Title

Part 84—Non-discrimination on the Basis of Handicap in Programs

Part 86—Nondiscrimination on the basis of sex in the admission of individuals to training programs

Part 91—Non-discrimination on the Basis of Age in Health and Human Services Programs or Activities Receiving Federal Financial Assistance

Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to States and Local Governments (**Federal Register**, March 11, 1988)

Part 93—New Restrictions on Lobbying

Part 100—Intergovernmental Review of Department of Health and Human Services Programs and Activities

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97N-0243]

### Review of the Current State of Science Relating to Detection and Control of Cyclospora on Fresh Produce; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition, is announcing a public meeting that will review the current state of the science relating to the detection and control of *Cyclospora* on fresh produce.

**DATES:** The public meeting will be held on Wednesday, July 23, 1997, from 8:30 a.m. to 5 p.m. Submit written notices of participation by July 11, 1997.

Registration must be received by July 11, 1997. Written comments will be accepted until August 8, 1997.

**ADDRESSES:** The public meeting will be held at the Marriott Metro Center, 775 12th St. NW., Washington, DC. Submit registration and written notices of participation to Catherine M. DeRoever (address below). Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Catherine M. DeRoever, Executive Operations Staff (HFS-22), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4251, FAX 202-205-4970, or email "cmd@fdacf.ssw.dhhs.gov".

Those persons interested in attending the public meeting should fax their name, title, firm name, address, and telephone number to Catherine M. DeRoever (fax number above).

Those persons interested in presenting information at the meeting should fax their name, title, firm name, address, telephone number, and an outline of their presentation to Catherine M. DeRoever (fax number above).

There is no registration fee for this public meeting, but advance registration is suggested. Interested persons are

encouraged to register early because space may be limited.

**SUPPLEMENTARY INFORMATION:** The purpose of this public meeting will be to provide an opportunity for an open discussion of the current state of the science, and a review of technological and safety factors, relating to the detection and control of *Cyclospora* on fresh produce. The public meeting will also provide an opportunity for consideration of other issues and data pertaining to the recent foodborne disease outbreak associated with this organism and fresh berries and lettuce.

This meeting is of special interest to the fresh produce industry, public health associations, and health agencies of State and local governments. It will provide an occasion for an open discussion and exchange of information on the following topics: All relevant safety factors, current research accomplishments and future research, measures that would reduce the risk of future outbreaks, and related issues.

The agenda will include presentations on such topics as: (1) Outbreak data, (2) growing and harvesting practices, (3) traceback efforts, (4) research, and (5) related issues.

The agency is interested in learning about all aspects of production and distribution of fresh produce. Both oral and written comments are encouraged on the following topics: (1) Appropriate current good manufacturing practices, (2) the current availability of sanitizing agents to control the organism, (3) technological/intervention strategies now available or becoming available that appear to be effective control measures, and (4) related issues.

The agency is encouraging individuals with information and data on these matters to present their comments. The agency encourages interested persons to address relevant safety considerations, identification of needed research, what measures should be taken to reduce the risk of future outbreaks, and related issues.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript of the public meeting and submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 19, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Application of Good Guidance Practices to Revisions to the Shellfish Sanitation Model Ordinance

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

**ACTION:** Notice.

**SUMMARY:** The Shellfish Sanitation Model Ordinance, which is part of the National Shellfish Sanitation Program (NSSP), contains procedures for the harvesting and processing of raw molluscan shellfish that the States belonging to the ISSC should adhere to if their shellfish are to be acceptable to the other States in the ISSC. The Model Ordinance is a Food and Drug Administration (FDA) guideline and, as such, is subject to FDA's policy relating to the development, issuance, and use of guidance documents. FDA is providing notice on how it intends to apply its policy on guidance documents to any revisions of the Model Ordinance that may result from the meeting of the Interstate Shellfish Sanitation Conference (ISSC) scheduled for July 12 through 18, 1997.

**ADDRESSES:** Submit written requests for copies of the issues that will be considered by the ISSC in July to Kenneth Moore, Executive Director, Interstate Shellfish Sanitation Conference, 115 Atrium Way, suite 117, Columbia, SC 29233.

**FOR FURTHER INFORMATION CONTACT:** Paul DiStefano, Center for Food Safety and Applied Nutrition (HFS-415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3149.

#### SUPPLEMENTARY INFORMATION:

##### I. Program for Molluscan Shellfish

FDA is responsible for enforcing, among other laws, the Federal Food, Drug, and Cosmetic Act and certain portions of the Public Health Service Act. These laws require that all foods shipped in interstate commerce, including molluscan shellfish, be prepared, packed, and held under sanitary conditions that will protect their safety; that they be honestly and informatively labeled; and that the food itself be safe, clean, and sanitary. FDA

is authorized to accept assistance from State and local authorities in the enforcement of laws to prevent and to suppress the spread of communicable disease (42 U.S.C. 243 and 21 U.S.C. 372).

This latter authority gave rise to the NSSP, which was initiated in 1925 and has continued to date as a voluntary FDA, State, and shellfish industry program. The safety of raw molluscan shellfish for human consumption begins with ensuring the quality of the water in which these sedentary organisms are grown and from which they are harvested. These waters are mostly State resources. Consequently, the NSSP is based on the premise that public health controls for raw molluscan shellfish can best be accomplished under State laws with Federal technical support and industry participation.

The success of the NSSP is largely dependent on the States adopting and implementing recommended requirements for the operation of effective programs. These recommended requirements, which traditionally have been incorporated into the NSSP "Manual of Operations," relate to the proper ways to classify and monitor shellfish growing areas, to harvest and process shellfish, to inspect processors, and to address other related matters.

The ISSC consists of agencies from shellfish producing and receiving States, FDA, the National Marine Fisheries Service of the U.S. Department of Commerce, and the shellfish industry. A primary purpose of the ISSC has been to provide a formal structure for these entities to provide input on the Manual of Operations.

Recently, the ISSC has chosen to reconstitute the Manual of Operations in the form of a Shellfish Sanitation Model Ordinance in order to facilitate uniform adoption by the member States. The use of the Model Ordinance is expected to begin on January 1, 1998. The Model Ordinance is an FDA guideline and as such, is subject to the policy of FDA relating to the development, issuance, and use of guidance documents, as expressed in the **Federal Register** of February 27, 1997 (62 FR 8961 at 8969 through 8971).

Since the Manual of Operations was written, FDA has published the manual and periodic revisions to it and has issued interpretations of its provisions. The agency expects to do the same with the Model Ordinance. FDA performs this function in accordance with a memorandum of understanding (MOU) entered into in 1984 between FDA and the ISSC.

The Model Ordinance is revised through a process that begins with