DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

Hanford Health Projects Inter-Tribal Council et al.; Notice of Meeting

Public meeting of the Inter-tribal Council on Hanford Health Projects (ICHHP) in association with the Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Hanford Health Effects Subcommittee.

Name: Public meeting of the Inter-tribal Council on Hanford Health Projects (ICHHP) in association with the Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Hanford Health Effects Subcommittee (HHES).

Time and Date: 9 a.m.–4:00 p.m., January 24, 2001.

Place: West Coast Tri-Cities Hotel, 1101 North Columbia Center Boulevard, Kennewick, Washington.

Telephone: (509) 783–0611.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background

Under a Memorandum of Understanding (MOU) signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC. Community Involvement is a critical part of ATSDR's and CDC's energy-related research and activities and input from members of the ICHHP is part of these efforts. The ICHHP will work with the HHES to provide input on American Indian health effects at the Hanford, Washington site.

Purpose: The purpose of this meeting is to address issues that are unique to tribal involvement with the HHES, and agency updates.

Matters to be Discussed: Agenda items will include a dialogue on issues that are unique to tribal involvement with the HHES. This will include updating tribal members of the cooperative agreement activities in environmental health capacity building and providing support for tribal involvement in and representation on the HHES. Agenda items are subject to change as priorities dictate.

CONTACT PERSONS FOR MORE INFORMATION: Dean Seneca, Executive Secretary, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE M/S E–54 Atlanta, Georgia 30333, telephone 1–888–42-ATSDR (28737), fax 404/639–4699.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 18, 2000.

Julia M. Fuller,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–32932 Filed 12–26–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the Shellfish and Seafood Safety Assistance Project; Notice to Accept and Consider a Single Source Application; Availability of Funds for Fiscal Year 2001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Seafood (OS) is announcing its intent to award, noncompetitively, a cooperative agreement to the Interstate Shellfish Sanitation Conference (ISSC) in the amount of $275,000 for the first year. Subject to the availability of Federal funds and successful performance, 4 additional years of support will be available. This effort will enhance FDA's molluscan shellfish sanitation program and provide the public greater assurance of the quality and safety of these products.

DATES: Submit application by January 26, 2001.

ADDRESSES: An application is available from and should be submitted to: Rosemary Springer, Grants Management Specialist, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182. If an application is hand-carried or commercially delivered, it should be addressed to rm. 2129, 5630 Fishers Lane, Rockville, MD 20857, FAX 301–827–7106, e-mail address: rspringe@oc.fda.gov.

FOR FURTHER INFORMATION CONTACT: *For the administrative and financial management aspects of this notice:* Rosemary Springer, Grants Management Specialist (address above).

Regarding the programmatic aspects: Paul W. Distefano, Office of Seafood (HFS–417), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204 202–418–3149.

SUPPLEMENTARY INFORMATION: This project is authorized under section 301 of the Public Health Service Act (42 U.S.C 241). This activity is generally described in the Catalog of Federal Domestic Assistance at 93.103. This application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100).

This project will: (1) Enhance both the effectiveness and uniformity of the molluscan shellfish program by: (a) Improving the flow of information between Federal and State regulatory agencies, industry, and the consumer, and (b) strengthening State activities by providing assistance in such areas as procedural and policy guidance, technical training, research, consumer education, and the assurance of conformity to the National Shellfish Sanitation Program (NSSP); and (2) provide for research on *Vibrio*

vulnificus, which, although not normally a threat to healthy individuals, can cause serious illness and death in individuals with certain preexisting conditions and on *Vibrio parahaemolyticus*, which can cause illness in healthy individuals as well as compromised individuals. This research is intended to provide information to establish science-based controls to protect consumers from *V. vulnificus* and *V. parahaemolyticus* infection.

I. Availability of Funds

FDA will fund this cooperative agreement at a level of approximately $275,000 for the first year. An additional 4 years of support will be available, depending upon fiscal year appropriations, continued support from other government agencies, and successful performance. It is anticipated that this cooperative agreement will commence on or before March 1, 2001. This project may be supplemented over the 5 year period based on annual appropriations language.

II. Background

Molluscan shellfish have been identified as the source of a majority of seafood-borne illnesses and are the subject of congressional, industry, and public concern. Therefore, FDA has given high priority to enhance the agency program and to provide the public greater assurance of the quality and safety of these products. One such enhancement has been the incorporation of FDA's seafood hazard analysis critical control point (HACCP) regulation into the NSSP Model Ordinance. FDA administers the NSSP and the NSSP Model Ordinance, which serves as guidance for State shellfish sanitation programs and State regulations concerning shellfish safety.

In 1982, the ISSC was formed to provide a formal structure wherein State regulatory authorities can establish updated guidelines and procedures for the uniform application of that guidance for the sanitary control of the shellfish industry. The ISSC is a voluntary organization and is open to all persons interested in fostering controls that will ensure sources of safe and sanitary shellfish. In 1984, FDA recognized the ISSC through a memorandum of understanding (MOU) and continues to recognize ISSC as the primary voluntary national organization of State shellfish regulatory officials that will provide guidance and counsel to the States on matters of sanitary control of shellfish.

In 1993, FDA awarded a noncompetitive grant to ISSC for 1 year and provided support for an additional 2 years because of satisfactory performance. FDA received $75,000 a year from the Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Services (NMFS) in support of the grant. Combined with the NMFS funds, the ISSC cooperative agreement was funded for a total of $465,000 over the 3 years.

In February 1996, FDA awarded another noncompetitive cooperative grant to ISSC for 1 year with an additional 4 years based on satisfactory performance. The approved funding level per year was $150,000.

A. Substantial Accomplishments Under the Initial 1996 ISSC Award Include:

1. Coordinated annual shellfish safety meetings of Federal regulators, State regulators, industry members for improving shellfish safety controls in the NSSP Model Ordinance.
2. Facilitated incorporation and implementation of HACCP into the NSSP Model Ordinance.
3. Facilitated the resolution of shellfish safety issues between several States and FDA.
4. Coordinated the revision of NSSP Model Ordinance and assisted in its distribution.
5. Coordinated development and oversight of an interim *V. parahaemolyticus* control plan.
6. Developed an educational training video concerning illegal shellfish harvesting.
7. Developed and maintained an Internet site for continuous accessibility to molluscan shellfish safety related information.

Starting in September 1996, FDA awarded supplemental funding to the ISSC cooperative agreement providing for the implementation and enhancement of activities associated with *V. vulnificus* and *V. parahaemolyticus*.

V. vulnificus is a pathogen found in the estuarine environment. *V. vulnificus* bacteria are not normally a threat to healthy individuals. However, for individuals with preexisting chronic medical conditions such as liver disease, alcoholism, and hemochromatosis, *V. vulnificus* can cause serious illness and death. Each year, between 12 and 40 cases of *V. vulnificus* illness associated with consumption of raw molluscan shellfish are reported to public health authorities in the United States.

V. parahaemolyticus is also a pathogen found in the estuarine environment and can cause serious illness and death to individuals with preexisting chronic medical conditions such as liver disease and alcoholism. But, unlike *V. vulnificus*, *V. parahaemolyticus* bacteria can cause illness in healthy individuals. Each year, sporadic cases of *V. parahaemolyticus* associated with raw molluscan shellfish consumption are reported to public health authorities in the United States. Recently, however, a number of *V. parahaemolyticus* outbreaks associated with consumption of raw shellfish from the northern Pacific Coast, northern Atlantic Coast, and Gulf Coast have occurred.

B. Substantial Accomplishments of the ISSC in Relation to V. Vulnificus and V. Parahaemolyticus Supplemental Funding Include:

1. Coordinated the development of shellstock time-temperature controls for *V. vulnificus* and *V. parahaemolyticus*.
2. Provided funding for *V. vulnificus* virulent strain identification research.
3. Provided funding for research on the effects of ice chilling on *V. vulnificus* and *V. parahaemolyticus*.
4. Provided funding for research on the influence of water and air temperature, dissolved oxygen, and nutrients on *V. parahaemolytics* concentrations in Pacific oysters.
5. Provided funding to conduct a retail study to define levels of *V. vulnificus* and *V. parahaemolytics* at points of purchase.
6. Provided funding to conduct an economic assessment of mandating post-harvest treatment of oysters.
7. Developed *V. parahaemolytics* laboratory methodology training video.
8. Developed and broadcasted a public service announcement for alerting at risk consumers of the dangers associated with raw shellfish consumption.

III. Purpose

The ISSC was formed as a partnership of State shellfish control officials representing both environmental and public health agencies; Federal agencies including FDA, the Environmental Protection Agency, and the Department of Commerce, NMFS; and representatives from industry, academia, and foreign governments and industry. More than 30 States are members of the ISSC, including all 23 coastal shellfish-producing States.

The proposed cooperative agreement with ISSC will continue: (1) To address the need to improve information exchange and transfer among States, Federal agencies, industry, and consumers; (2) to strengthen State activities by providing them with procedural and policy guidance, technical training, research, and consumer education; and (3) to enhance

research efforts and projects which will contribute significantly to the ISSC/FDA ability to identify scientifically defensible controls which reduce the incidence of *V. vulnificus* and *V. parahaemolyticus* illness.

IV. Substantive Involvement by FDA

1. FDA will monitor and evaluate the ISSC's overall conduct under this cooperative agreement.
2. FDA will have representation on the ISSC executive board, committees, and task forces.
3. FDA will collaborate and work closely with ISSC on *V. vulnificus* and *V. parahaemolyticus* (e.g. continue to work on developing the *V. vulnificus* consumer education program and monitoring the implementation of the *V. parhaemolyticus* control plan).
4. FDA will continue to work with ISSC to develop State program evaluation criteria (e.g. developing a *Vibrio* retail study that could include laboratory analyses of shellfish.)
5. FDA will analyze State shellfish program data and information for ISSC.
6. FDA will conduct training courses in growing area classification, plant sanitation, HACCP and plant standardization for participants of the ISSC.
7. FDA will work with ISSC to develop new microbiological techniques and to develop and implement early warning systems for toxic algal blooms.
8. FDA will continue to work with ISSC to establish a mechanism for incorporating new lab methods into the NSSP and to develop NSSP Model Ordinance interpretations.
9. FDA will take any action that may be necessary to ensure compliance with this cooperative agreement (e.g. conducting economic study on post harvest treatment processes and developing patrol and plant inspection criteria).

V. Review Procedures and Evaluation Criteria

A. Review Procedures

The application submitted by the ISSC will undergo noncompetitive dual peer review. The application will be reviewed for scientific and technical merit by a panel of experts based upon the applicable evaluation criteria. If the application is recommended for approval, it will then be presented to the National Advisory Environmental Health Sciences Council for their concurrence.

B. Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

1. The application clearly states an understanding of the purpose and objectives of the cooperative agreement in the overall seafood safety program and *Vibrio* research.
2. The application clearly describes the steps and a proposed schedule for planning, implementing and accomplishing the activities to be carried out under the cooperative agreement.
3. The application describes the applicant's ability to perform the responsibilities under this project by providing qualified staff. The application also demonstrates that the ISSC has the financial and other resources required for this project.
4. The application specifies the approach that the ISSC will use to maintain and to continue working with both the States and industry to ensure the exchange of information among the States, industry, and consumers on seafood safety.
5. The application specifies how the ISSC monitors the progress of the *V. vulnificus* and *V. parahaemolyticus* research projects and keeps the FDA informed of any significant advances in the understanding of or control of *V. vulnificus* and *V. parahaemolyticus*.

In addition, the agency will determine whether the estimated cost of the project is reasonable. The application shall include a detailed budget that shows: (1) Anticipated costs for personnel, travel, communications and postage, equipment, and supplies; and (2) the sources of funds to meet those needs.

VI. Reporting Requirements

FDA requires an annual Financial Status Report (FSR) (SF–269). Under FDA procedures, the original and two copies of this report must be submitted to FDA's Grants Management Office within 90 days of the budget period expiration date.

An annual project progress report is required and the contents shall be suggested by the project officer.

The annual progress report on the *V. vulnificus* and *V. parahaemolyticus* research projects shall include, but is not limited to, the following: (1) Listing and purpose of research projects funded, (2) cost of each project, (3) milestones and completion dates for each project, (4) year-to-date results/scientific findings/public health findings of each project, (5) potential *V. vulnificus* and *V. parahaemolyticus* and control measures/strategies suggested by research efforts.

A final project progress report, FSR, and invention statement must be submitted within 90 days from the expiration date of the project period as noted on the notice of grant award.

Program monitoring will be conducted on an ongoing basis. Monitoring may be in the form of telephone conversations between the project officer/grants management specialists and the principal investigator. Site visits may be made by either program or grants management staff. The results of the visits will be recorded in the official grant file and may be available to the grantee upon request.

VII. Mechanism of Support

Support for this project will be in the form of a cooperative agreement. This agreement will be subject to all policies and requirements that govern the research grant programs of the Public Health Service, including provisions of 42 CFR part 52 and 45 CFR part 74.

VIII. Submission Requirements

The original and two copies of the completed grant application form PHS 398 (Rev. 4/98) with copies of the appendices for each of the copies, should be submitted to Rosemary Springer (address above). Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

IX. Legend

Unless disclosure is required the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: December 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–33087 Filed 12–22–00; 10:47 am]

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