new editions of the Guide as knowledge and technology advance about fish and fishery products hazards and controls.

Under the act and its implementing regulations, processors are responsible for ensuring that their HACCP systems are adequate. If processors need help in developing a HACCP system, the Guide provides them with information that can help them put in place a HACCP system that should generally satisfy a processor's obligations under the seafood HACCP regulation. However, as the Guide itself makes clear, the materials contained in the Guide consist of recommendations, and not binding requirements. Processors may control hazards in other ways so long as they can demonstrate that their approaches are scientifically defensible. Processors may also rely on hazard analyses that differ from those in the Guide so long as they can demonstrate that their own analyses are valid for their particular circumstances.

As a general matter, processors should establish the adequacy of a hazard analysis or control before implementing it. FDA can envision circumstances, however, where the industry could make a strong threshold case for the validity of a particular hazard analysis or system of controls even though complete confirmation of its validity was not yet available from scientific studies.

FDA believes that a mandatory HACCP program should serve as a catalyst for research and science-based resolution of food safety questions. Thus, where the consuming public would not be placed at risk, FDA believes it is appropriate to use a mechanism that encourages the resolution of legitimate scientific questions before they become legal controversies.

The purpose of this notice is to propose and obtain comment on guidance on the submission of citizen's petitions under § 10.30 (21 CFR 10.30), whereby any member of the public may request that FDA consider exercising enforcement discretion on certain matters under the seafood HACCP regulations pending their scientific resolution. This proposed guidance applies to issues involving matters of scientific fact related to whether a hazard is reasonably likely to occur or whether a control is sufficient, the resolution of which is likely only after the completion of a scientific study or a search of existing scientific literature. Other issues that relate to broader policy, such as circumstances where regulations specify hazards that are reasonably likely to occur in certain situations or enumerate performance standards or the actual critical limits that must be met, may also be addressed by filing a citizen's petition, or by discussing the issue directly with the agency in a less formal manner, but are not within the scope of this proposed guidance.

FDA anticipates that matters for which limited enforcement discretion will be considered will be narrow. In determining whether to exercise enforcement discretion, the agency may consider, among other things, whether the position presented by the petitioner has sufficient scientific merit and whether the petitioner's proposal is appropriate and adequate to answer the necessary scientific questions (e.g., whether the study and/or literature search that will be undertaken will, in the agency's judgment, provide the information needed to support the requested change; whether the identification of the time necessary to complete the study and any data analysis is reasonable; whether the petitioner commits to keeping FDA apprised of the progress being made on the study plan over the course of the study; and whether the petitioner agrees to provide FDA with all data from the study in order to advance the public state of knowledge, regardless of the outcome of the study).

FDA recommends that such petitions be submitted as requests to revise or amend the Guide. If a party believes that the Guide should be revised based on scientific data to be provided at a later date, the party should submit a petition under § 10.30 to the Dockets Management Branch (address above). Petitions must comply with the requirements of § 10.30. In addition, interested persons are encouraged to discuss the contents of an intended petition in advance of submission with representatives of FDA's Office of Seafood either in person or by telephone (202–418–3133). Such communication may minimize misunderstandings and time-consuming written communication during the consideration process.

If FDA determines, after reviewing a request, that it is appropriate for the agency to exercise enforcement discretion, the agency will advise the requester in writing that the agency does not anticipate enforcement action for the practice at issue and will post the letter on its Internet website at ''http://www.fda.gov''. FDA will also advise the requester of the time period that the agency believes is reasonable for the study and data analysis. If, at the end of this timeframe, the agency concludes that the data from the study are inadequate, or if no data are submitted, FDA will proceed with its regulatory options. The agency may also reconsider the use of enforcement discretion before the end of the timeframe if circumstances change or otherwise warrant reconsideration. If such reconsideration takes place, FDA will notify the original requester and make its reconsideration public.

In considering the information submitted, FDA will evaluate, as appropriate: (1) The methodology of the scientific study; (2) the scientific merit of the conclusions; and (3) the consistency of the recommended action with agency policy. Any changes in agency position will be posted on FDA's Internet website at ''http://www.fda.gov'' and then reflected in the next edition of the Guide.

The public is reminded that it is welcome to discuss with the agency at any time, including before finalization of this guidance, issues relating to seafood hazards and controls and how these issues may be resolved through research.

The guidance provided in this notice represents the agency's current thinking on the subject and does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

FDA tentatively concludes that this guidance would not impose any paperwork burden that has not already been approved by OMB under OMB No. 0910–0183 ''Citizen Petition—21 CFR 10.30.'' These guidelines simply provide information to the public to assist them in submitting citizen petitions to obtain changes in the Guide under certain circumstances.

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7363 Filed 3–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should

notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Aging.

Date: May 27–28, 1999.

Open: For the Director's Status Report, presentation on the NNA Program Review, Center for Inherited Disease Research, and Report on the Minority Aging Task Force.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Open: May 28, 1999, 8:00 am to 9:30 am.

Agenda: Report on Working Group on Program.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Closed: May 28, 1999, 9:30 am to adjournment.

Agenda: To review and evaluate grant applications.

Place: 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Contact Person: Miriam F. Kelty, Director, Office of Extramural Affairs, National Institute of Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, MD 20892, 301–496–9322.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 22, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–7504 Filed 3–25–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(b)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, K–12 RFA.

Date: April 15, 1999.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, Chevy Chase Pavilion, 4300 Military Rd., Wisconsin at Western Ave., Washington, DC 20015.

Contact Person: Gopal M. Bhatnagar, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, PHS, DHHS, 9000 Rockville Pike, 6100 Bldg., Room 5E01, Bethesda, MD 20892, (301) 496–1485.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.865, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: March 22, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–7505 Filed 3–25–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussion could disclose confidential trade secretes of commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel HYPOXIA IN DEVELOPMENT: INJURY AND ADAPTATION MECHANISMS.

Date: April 6–7, 1999.

Time: 7:30 PM to 2:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn at Yale, 30 Whalley Avenue, New Haven, CT 06511.

Contact Person: Gopal M. Bhatnagar, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, PHS, DHHS, 900 Rockville Pike, 6100 Bldg., Room 5E01, BETHESDA, MD 20892, (301) 496–1485.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: March 22, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–7506 Filed 3–25–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel NIEHS SEP: Growth Factors in Asbestos Induced Pulmonary Fibrosis.

Date: April 7–9, 1999.

Time: April 7, 1999, 7:00 PM to 10:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Downtown-Superdome, 330 Loyola Avenue, New Orleans, LA 70112.

Time: April 8, 1999, 4:00 PM to 8:00 PM.