880TH—MEETING, FEBRUARY 9, 2005, REGULAR MEETING, 10 A.M.—Continued

| Item No. | Docket No. | Company |
|---|---|---|
| | RP04–280–000 | Northern Natural Gas Company. |
| | RP04–94–000 | Northern Natural Gas Company. |
| G–10 | OR05–2–000 | State of Alaska v. BP Pipelines (Alaska) Inc., ExxonMobil Pipeline Company, ConocoPhillips Transportation Alaska, Inc., Unocal Pipeline Company and Koch Alaska Pipeline Company. |
| | OR05–3–000 | Anadarko Petroleum Corporation v. TAPS Carriers. |
| | IS05–72–000 | ExxonMobil Pipeline Company. |
| | IS05–80–000 | ConocoPhillips Transportation Alaska, Inc. |
| | IS05–82–000 | BP Pipelines (Alaska) Inc. |
| | IS05–96–000 | Koch Alaska Pipeline Company. |
| | IS05–107–000 | Unocal Pipeline Company. |
| G–11 | PR97–1–003 | Consumers Power Company. |
| G–12 | TS04–53–002 | Destin Pipeline Company, L.L.C. |
| | TS05–2–001 | Energy West Development. |
| | TS04–280–001 | Jupiter Energy Corporation. |
| | TS04–258–000 | Nornew Energy Supply, Inc. |
| | TS04–7–003 | ONEOK, Inc., and OkTex Pipeline Company. |
| | TS04–7–002 | ONEOK, Inc., and OkTex Pipeline Company. |
| G–13 | RP04–249–004 | AES Ocean Express LLC. |
| | **ENERGY PROJECTS—HYDRO** | |
| H–1 | P–460–029 | City of Tacoma, Washington. |
| H–2 | P–2816–032 | Vermont Electric Cooperative. |
| H–3 | P–2493–016 | Puget Sound Energy, Inc. |
| H–4 | P–1864–019 | Upper Peninsula Power Company. |
| H–5 | P–2149–119 | Public Utility District No. 1 of Douglas County, Washington. |
| | **ENERGY PROJECTS—CERTIFICATES** | |
| C–1 | RM05–1–000 | Regulations Governing the Conduct of Open Seasons for Alaska Natural Gas Transmission Projects. |
| C–2 | CP04–373–000 | Texas Gas Transmission, LLC. |
| C–3 | CP04–64–001 | Trunkline Gas Company, LLC. |
| C–4 | CP04–396–000 | Transcontinental Gas Pipe Line Corporation. |

**Magalie R. Salas,**

*Secretary.*

The Capitol Connection offers the opportunity for remote listening and viewing of the meeting. It is available for a fee, live over the Internet, via C-Band Satellite. Persons interested in receiving the broadcast, or who need information on making arrangements should contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100) as soon as possible or visit the Capitol Connection Web site at *http://www.capitolconnection.gmu.edu* and click on ''FERC''.

[FR Doc. 05–2479 Filed 2–3–05; 4:26 pm]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Meeting, Notice of Vote, Explanation of Action Closing Meeting and List of Persons To Attend

February 2, 2005.

The following notice of meeting is published pursuant to Section 3(a) of the Government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

**AGENCY HOLDING MEETING:** Federal Energy Regulatory Commission.

**DATE AND TIME:** February 9, 2005. (Within a relatively short time after the Commission's open meeting on February 9, 2005.)

**PLACE:** Room 3M 4A/B, 888 First Street, NE., Washington, DC 20426.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:** Non-public investigations and inquiries, enforcement related matters, and security of regulated facilities.

**CONTACT PERSON FOR MORE INFORMATION:** Magalie R. Salas, Secretary, Telephone (202) 502–8400.

Chairman Wood and Commissioners Brownell, Kelliher, and Kelly voted to hold a closed meeting on February 9, 2005. The certification of the General Counsel explaining the action closing the meeting is available for public inspection in the Commission's Public Reference Room at 888 First Street, NW., Washington, DC 20426.

The Chairman and the Commissioners, their assistants, the Commission's Secretary and her assistant, the General Counsel and members of her staff, and a stenographer are expected to attend the meeting. Other staff members from the Commission's program offices who will advise the Commissioners in the matters discussed will also be present.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 05–2480 Filed 2–3–05; 4:33 pm]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**RIN: 2070–AD57**

**[OPP–2003–0132; FRL–7695–4]**

### Human Testing; Proposed Plan and Description of Review Process

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's plan to establish a comprehensive framework for making decisions about the extent to which it will consider or rely on certain types of research with human participants. Among other actions the plan provides for: Issuing proposed and final rules, and providing in this Notice a description of the Agency's case-by-case process for evaluating human studies, which is to

remain in effect until superseded by rulemaking. This Notice invites public comments on the overall plan and particularly on the current case-by-case process.

**DATES:** Comments must be received on or before May 9, 2005.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number OPP–2003–0132, by one of the following methods:

- *Agency website*: *http://www.epa.gov/edocket/*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- *E-mail*: Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2003–0132.
- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0132.
- *Hand delivery*: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2003–0132. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions*: Direct your comments to docket ID number OPP–2003–0132. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL–7181–7).

*Docket:* All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** William L. Jordan, Mailcode 7501C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–305–1049; fax number: 703–308–4776; e-mail address: *jordan.william@epa.gov*.

**SUPPLEMENTARY INFORMATION:** This Notice is organized into five Units. Unit I. contains ''General Information'' about the applicability of this Notice, how to obtain additional information, how to submit comments in response to the request for comments, and certain other related matters. Unit II. provides background and historic information pertaining to human subject research. Unit III. describes the activities that EPA is planning to pursue to establish a framework within which it will address the broad range of issues related to the Agency's consideration of or reliance on research with human participants. Unit IV. describes the current case-by-case process that EPA will continue to follow pending completion of the rulemaking efforts described in its plan. The last unit describes procedures followed in the development of this Notice and certain statutes and Executive Orders that the public may wish to consider in preparing comments.

## I. General Information

### *A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of particular interest to those who conduct testing of substances regulated by EPA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### *B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET, *http://www.epa.gov/edocket/*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

### *C. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov, or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

## II. Introduction

### *A. Background on Federal Standards for Conducting Human Research*

Over the years, scientific research with human subjects has provided much valuable information to help characterize and control risks to public health, but its use has also raised particular ethical concerns for the welfare of the human participants in such research as well as scientific issues related to the role of such research in assessing risks. Society has responded to these concerns by defining general standards for conducting human research.

In the United States, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued in 1979 *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. This document can be found on the web at *http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm*. For many Federal agencies and departments in the United States, the principles of the Belmont Report are implemented through the Federal Policy for the Protection of Human Subjects (also known as the Common Rule). The Common Rule, which was promulgated by 15 Federal departments and agencies, including the EPA, on June 18, 1991 (56 FR 28003), applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal department or agency that has adopted the Common Rule and has taken appropriate administrative action to make it applicable to such research. The Common Rule as promulgated by EPA (40 CFR part 26) has applied to human subjects research conducted or supported by EPA since it was put into place in 1991.

More broadly, the international medical research community has developed and maintains ethical standards documented in the Declaration of Helsinki, first issued by the World Medical Association in 1964 and revised several times since then. The latest version of the Declaration is available at: *http://www.wma.net/e/policy/b3.htm*. These standards apply to research on matters relating to the diagnosis and treatment of human disease, and to research that adds to understanding of the causes of disease and the biological mechanisms that explain the relationships between human exposures to environmental agents and disease.

In addition, many public and private research and academic institutions and private companies, both in the United States and in other countries, including non-federal U.S. and non-U.S. governmental organizations, have their own specific policies related to the protection of human participants in research.

Much of the scientific information supporting EPA's actions is generated by researchers who are not part of or supported by a Federal agency, including a significant portion of the research with human subjects submitted to the Agency or retrieved by the Agency from published sources. Such research, referred to here as ''third-party'' research, may be governed by specific institutional policies intended to protect research participants, may fall within the scope of the Declaration of Helsinki, or might actually be covered by the Common Rule if the particular testing institution holds an assurance approved for federalwide use by the Department of Health and Human Services' (HHS) Office for Human Research Protections and the institution has voluntarily extended the applicability of the assurance to such research. In some instances, research is reported in such a manner that EPA cannot readily determine whether institutional policies are consistent with or as protective of human subjects as the Common Rule, or even the extent to which such policies or standards have been followed in the conduct of any particular study. Thus, even well-conducted third-party human studies may raise difficult questions for the Agency when it seeks to determine their acceptability for consideration. Unit IV. of this Notice contains a description of EPA's case-by-case process for review of third-party human studies.

### *B. Human Research Issues in EPA's Pesticide Program*

Although data from human studies has contributed to assessments and decisions in most EPA programs, issues about consideration of and reliance on third-party human research studies have arisen most frequently, but not exclusively, with respect to pesticides. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is authorized to require pesticide companies to conduct studies with human subjects, for example, to measure potential exposure to pesticide users or to workers and others who re-enter areas treated with pesticides, or to evaluate the effectiveness of pesticide products intended to repel insects and other pests from human skin. In addition, EPA sometimes encourages other research with human subjects, including tests of the potential for some pesticides--generally those designed for prolonged contact with human skin--to irritate or sensitize human skin, and tests of the metabolic fate of pesticides in the human body. These latter studies typically precede monitoring studies of agricultural workers and others to protect them from exposure to potentially dangerous levels of pesticide residues.

In addition to these kinds of research which have been required or encouraged by EPA, other kinds of studies involving human subjects intentionally exposed to pesticides have occasionally been submitted to the agency voluntarily. Among these voluntarily submitted studies have been tests involving intentional dosing of human subjects to establish a No Observed Adverse Effect Level (NOAEL) or No Observed Effect Level (NOEL) for systemic toxicity of certain pesticides to humans. (Often the researchers reported observing no treatment-related responses in test participants.) For some two decades before passage of the Food Quality Protection Act (FQPA) in 1996, submission of such studies was rare. EPA considered and relied on human NOAEL/NOEL studies in a few regulatory decisions on pesticides made prior to 1996. After passage of FQPA, submission of these types of studies to EPA's Office of Pesticide Programs increased; the Agency has received some 20 studies of this kind since 1996.

In response to concerns about human testing expressed in a report of a non-governmental advocacy organization, the Environmental Working Group, in July 1998, the Agency began a systematic review of its policy and practice. In a press statement on July 28, 1998, EPA noted that it had not relied on any such studies in any final decisions made under FQPA.

In further response to growing public concern over pesticide research with human subjects, EPA convened an advisory committee under the joint auspices of the EPA Science Advisory

Board (SAB) and the FIFRA Scientific Advisory Panel (SAP) to address issues of the scientific and ethical acceptability of such research. This advisory committee, known as the Data from Testing of Human Subjects Subcommittee (DTHSS), met in December 1998 and November 1999, and completed its report in September 2000. Their report is available in the Docket cited above in this Notice, and on the web at: *http://www.epa.gov/science1/pdf/ec0017.pdf*.

The DTHSS advisory committee heard many comments at their two public meetings, and further comments have been submitted in response to their published report. No clear consensus emerged from the advisory committee process on the acceptability of NOAEL or NOEL studies of systemic toxicity of pesticides to human subjects, and significant differences of opinion remained on both their scientific merit and ethical acceptability. A vigorous public debate continued about the extent to which EPA should accept, consider, or rely on third-party intentional dosing human toxicity studies with pesticides.

In December 2001, EPA asked the advice of the National Academy of Sciences (NAS) on the many difficult scientific and ethical issues raised in this debate, and also stated the Agency's interim approach on third-party intentional dosing human subjects studies. The Agency's press release on this subject is on the web at *http://yosemite.epa.gov/opa/admpress.nsf/b1ab9f485b098972852562e7004dc686/c232a45f5473 717085256b2200740ad4?OpenDocument*. At that time the Agency committed that when it received the NAS report, ''EPA will engage in an open and participatory process involving federal partners, interested parties and the public during its policy development and/or rulemaking regarding future acceptance, consideration or regulatory reliance on such human studies.'' In addition, the press release also stated that while the Academy was considering these issues, EPA ''will not consider or rely on any such human studies in its regulatory decision-making.''

In early 2002, various parties from the pesticide industry filed a petition with the U. S. Court of Appeals for the District of Columbia for review of EPA's December 2001 press release. These parties argued that the Agency's interim approach constituted a ''rule'' promulgated in violation of the procedural requirements of the Administrative Procedure Act and the Federal Food, Drug, and Cosmetic Act. On June 3, 2003, the Court of Appeals concluded that:

> For the reasons enumerated above, we vacate the directive articulated in EPA's December 14, 2001 Press Release for a failure to engage in the requisite notice and comment rulemaking. The consequence is that the agency's previous practice of considering third-party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide, is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation.

See *Crop Life America v. Environmental Protection Agency*, 329 F.3d 876, 884 - 85 (D.C. Cir. 2003) (referred to as the *Crop Life America* case).

In the meantime, under a contract with EPA, the NAS convened a committee to provide the requested advice. The committee met publicly in December 2002, and again in January and March 2003. The membership, meeting schedule, and other information about the work of this committee can be found on the NAS website at: *http://www4.nas.edu/webcr.nsf/5c50571a75df494485256a95007a091e/9303f725c15902f685256c44005d8931?OpenDocument&Highlight=0,EPA*. The committee issued its final report, ''Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues,'' in February 2004. That report is available at: *http://www.nap.edu/books/0309091721/html/*.

On May 7, 2003, EPA issued an advance notice of proposed rulemaking (ANPR) on Human Testing (68 FR 24410) in which EPA announced its intention to undertake notice-and-comment rulemaking on the subject of its consideration of or reliance on research involving human participants. The ANPR also invited public comment on a broad range of issues related to this subject. EPA received over 600 submissions in response to the ANPR. Approximately 15 were from pesticide companies, pesticide users, and associated trade associations and groups. These comments mostly favored the Agency's use of data from scientifically sound, ethically appropriate studies conducted with human participants. Several of these groups urged EPA to apply the Common Rule to human research conducted for EPA by third parties. About 60 submissions came from religious groups, farm-workers' and children's advocacy groups, and environmental and public health advocacy organizations. Most of these groups generally opposed EPA's consideration of results from human testing, especially those involving intentional dosing of test participants with pesticides, on ethical grounds. Some of these commenters suggested, however, that, under certain strict conditions, EPA might appropriately consider data from human studies that complied with the Common Rule. Over 500 private citizens sent identical comments opposing the use of data from human studies with pesticides in EPA's regulatory decision-making. A sizeable number of other private citizens expressed dismay in their comments at what they misunderstood to be an EPA proposal to test pesticides on human subjects.

### *C. EPA's Agency-wide Focus on Human Research Issues*

Human research issues affect all programs in EPA. In its Office of Research and Development, EPA conducts research with human subjects to provide critical information on environmental risks, exposures, and effects in humans. This is referred to as first-party research. In both its Office of Research and Development and its program offices (including the Office of Air and Radiation, the Office of Water, the Office of Solid Waste and Emergency Response, and the Office of Prevention, Pesticides and Toxic Substances), EPA also supports research with human subjects conducted by others. This is referred to as second-party research. In all this work EPA has been and remains committed to full compliance with the Common Rule. This research has provided many important insights and has contributed to the protection of human health. The Agency will continue to conduct and support such research, and to consider and rely on its results in Agency assessments and decisions.

EPA also remains committed to scientifically sound assessments of the hazards of environmental agents, taking into consideration all available, relevant, and appropriate scientific research. In at least some cases, some of the available, relevant, and appropriate scientific research is conducted with human subjects by third parties, without Federal government support. EPA programs have on occasion relied on such studies to more completely characterize and understand environmental risks to humans; the Agency will continue to do so when it is appropriate.

EPA recognizes that its approach to the issues surrounding human research needs to be consistent across the Agency. EPA is interested in addressing the broad range of issues involving the consideration of and reliance on data from human subjects studies, particularly tests conducted by third

parties. After consideration of the Court of Appeals' decision in the *Crop Life America* case, the public comments on the ANPR, and the report from the NAS, EPA has concluded that it should undertake a number of activities to address these issues fully. The Agency's plan is described in Unit III. of this Notice.

*D. Legal Authority*

The actions described below are authorized under a variety of provisions of the different environmental statutes EPA administers. Section 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) gives the Administrator authority to ''prescribe regulations to carry out the purposes of [FIFRA].'' Such a rule would implement EPA's authority to require data in support of registration of pesticides (see, for example, FIFRA sections 3(c)(1)(F) and 3(c)(2)(B)) and to interpret the provision making it unlawful for any person ''to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.'' (FIFRA section 12(a)(2)(P)). In addition, section 408(e)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes the Administrator to issue a regulation establishing ''general procedures and requirements to implement this section.''

The Clean Air Act authorizes the Administrator to promulgate regulations necessary to carry out the Agency's functions under that Act at 42 U.S.C. 7601(a). The Clean Water Act contains a comparable provision at 33 U.S.C. 1361. Section 42 U.S.C. 9615 in the Comprehensive Environmental Response, Compensation, and Liability Act authorizes the President to establish regulations to implement the statute; this authority has been delegated to EPA by Executive Order 12580. The Emergency Planning and Community Right-to-Know Act also contains a general rulemaking provision, 42 U.S.C. 11048, authorizing the Administrator to promulgate rules necessary to carry out the Act. The Resource Conservation and Recovery Act specifically authorizes the Administrator to prescribe regulations necessary to carry out EPA's functions under the Act, 42 U.S.C. 6912. The Safe Drinking Water Act contains similar language, authorizing the Administrator to prescribe such regulations ''as are necessary and appropriate'' to carry out EPA's functions under the Act, 42 U.S.C. 300j-9. In addition, EPA has broad authority under 5 U.S.C. 301 and 42 U.S.C. 300v-1(b).

## III. EPA's Proposed Plan for Addressing Issues Relating to Human Testing

As a consequence of the public debate over whether it is appropriate to consider or rely on data from intentional dosing of humans, EPA recognizes that it is essential that the Agency state its positions on these issues so that the public can understand under what circumstances the Agency would take particular actions. The public debate has made clear that a number of aspects of EPA's policy and procedures are affected and that changes should be considered. Thus, EPA has identified a number of activities including the issuance of a clarifying description of the current case-by-case approach, rulemakings, and administrative/organizational changes that appear appropriate. EPA's overall goals for these activities are: That human participants in any research required by, conducted for, or considered by EPA are treated ethically; and that all scientifically sound data relevant to EPA decision-making is considered and used appropriately in reaching decisions under our authorities.

EPA has identified a variety of activities that, collectively, will establish a comprehensive framework to address the broad range of issues relating to the consideration of or reliance on data from human studies, particularly when conducted by third parties. EPA has drawn heavily on the recommendations contained in the NAS report in designing this framework.

1. *Publication of a clarifying description of the current case-by-case review of completed third-party human studies.* Consistent with the Court's opinion in the *Crop Life America* case, EPA will continue to evaluate third-party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide, until such time as this practice is replaced by a rulemaking. EPA is issuing a clarifying description of its current process in Unit IV. of this Notice. EPA intends to continue this process until such time as it is superseded by rulemaking. EPA, however, welcomes public comment on the description of its current process, and after reviewing comments, EPA may choose to publish additional clarification.

2. *Intent to publish a policy statement to third parties encouraging them to submit protocols for proposed human studies to EPA for review.* EPA intends to develop and make public a policy statement that encourages, but does not require, ''third-party'' researchers, i.e., researchers who are not part of or supported by a Federal agency, who are planning to conduct studies involving human participants to support an EPA regulatory decision, to submit a proposed protocol to EPA prior to conducting the research. The policy statement would explain EPA's intent to review and provide comments to the researcher concerning the ethical and scientific attributes of the proposal.

3. *Intent to publish guidance concerning compliance with the Common Rule for any future human studies specifically required by EPA.* EPA intends to publish non-binding guidance reflecting its plans to extend the Common Rule to specifically cover third-party human subject studies that are intended to be submitted to the Agency either voluntarily or in response to an Agency-imposed requirement and setting forth its expectation that any such study intended to be submitted in the interim should endeavor to include protections such as those included in the Common Rule.

Additionally, in the interim, the Agency intends to utilize existing authority, where appropriate, to require that test sponsors and testing facilities and personnel adhere to the Common Rule in conducting human studies if such studies are submitted to the Agency to satisfy specific data requirements, for example, studies with human participants that may be submitted to the Agency to satisfy data requirements under FIFRA section 3(c)(2)(B) or pursuant to a TSCA section 4 testing rule.

4. *Intent to conduct outreach to scientific journals encouraging improved reporting of the ethics of published human studies.* Many biomedical journals have adopted voluntary, uniform requirements for submitted manuscripts. These requirements include reporting on the protection of human subjects, through indicating whether the procedures followed were in accordance with the ethical standards of the responsible institution and with the Declaration of Helsinki or other, comparable, ethics codes. EPA intends to conduct outreach to these journals to determine the extent of coverage and compliance, and to encourage the reporting of this ethics information in connection with publication of the results of research conducted with human participants.

5. *Intent to expand the functions of the EPA Human Subjects Research Review Official and to relocate the HSRRO office.* Within EPA, the Human Subjects Research Review Official (HSRRO) has responsibility for assuring

that all human subjects research that is conducted or supported by EPA complies with the requirements of the Common Rule. The HSRRO's specific responsibilities are described in EPA Order 1000.17 Change A1. See *http://www.epa.gov/oamrtpnc/forms/1000_17a.pdf*. These responsibilities, in effect, entail addressing the scientific and ethical issues raised by human studies. The HSRRO reviews and approves about 50 projects a year, of which only a few involve intentional dosing of human participants with environmental pollutants. Currently, the HSRRO is located within EPA's Office of Research & Development, which is the Office within EPA that conducts or sponsors most of the research programs reviewed by the HSRRO.

The NAS report included the recommendation that ''[t]o ensure intentional dosing human studies conducted for EPA regulatory purposes meet the highest scientific and ethical standards, EPA should establish a Human Studies Review Board to address in an integrated way the scientific and ethical issues raised by such studies.'' The NAS further recommended that the Human Studies Review Board ''should report directly to the Office of the [EPA] Administrator.'' Consistent with the NAS recommendation, EPA intends to expand the functions of the HSRRO and is looking at where to relocate those functions. In addition to the existing function of ensuring compliance with the Common Rule for human subjects research conducted or supported by EPA, the Agency intends that the HSRRO will have responsibility for overseeing implementation of the ethics screening of completed studies (see Unit IV.), overseeing the review of proposals to conduct new human studies, identifying emerging ethical issues for research not subject to the Common Rule, and developing additional policies, training, and best practices guidance. The Agency welcomes public comment on this part of its plan.

6. *Intent to pursue rulemaking*. EPA intends to publish a proposed rule to make the provisions of the Common Rule, 40 CFR part 26, applicable to certain newly conducted third-party human studies and may propose to adopt some or all of the HHS regulations that provide additional protections for certain populations of vulnerable subjects. These HHS regulations are contained in HHS regulations at 45 CFR part 46, subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research), subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects), and subpart D (Additional Protections for Children Involved as Subjects in Research), and apply to all research involving these respective vulnerable subject groups that is conducted or supported by HHS. This proposal may also require a sponsor or investigator to provide to EPA, for prior review and approval, the protocol for certain human studies. EPA will also consider whether to propose a rule applying to certain previously conducted human studies. In developing its proposals, EPA will consider both the report from the NAS and public comments on the ANPR and this Notice.

## IV. Description of EPA's Current Case-by-Case Review Process for Third-Party Human Studies

This unit describes the Agency's process for reviewing and relying on completed, third-party studies that involve intentional dosing of human participants to identify or quantify a toxic endpoint. It is important to note that this is a case-by-case process. As such, it binds no one to a particular process or result--not the regulated community, not advocacy groups, not the public, and not EPA. Therefore, in any decision before EPA, any stakeholder may urge EPA to: (1) Conclude that this process is inapplicable; (2) consider factors other than those described here; or (3) make an exception to the process as described. EPA notes that it may determine, based on individual circumstances to act at variance from the review process as described. Thus, affected parties should not assume that EPA will follow a prescribed method of reviewing a particular human study in each and every instance. In any action involving consideration and review of a third-party, intentional dosing human study, EPA will explicitly state the basis upon which such a study has been evaluated.

As mandated by the D.C. Circuit in the *Crop Life America* case, EPA has resumed consideration of third-party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide. In its consideration and review of human studies submitted to the Agency, EPA will continue to generally accept scientifically valid studies unless there is clear evidence that the conduct of those studies was fundamentally unethical (e.g., the studies were intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the study was conducted. The Agency notes that this approach is consistent with Recommendation 5-7 of the February 2004, NAS report.

Primary responsibility for conducting case-by-case science and ethics reviews of third-party, intentional dosing human studies for toxic effects is vested in the EPA Office responsible for the relevant Agency action or risk assessment. To maintain high ethical standards the Agency screens all ''priority'' studies involving intentional dosing of human participants for toxic effects for existing ethics and scientific review information, and the responsible Office documents such reviews. A priority study is one which is expected to significantly affect the assessment, either by itself or as a substantial component of the weight of evidence, in determining: A regulatory standard, decision, or risk assessment value; determining an uncertainty factor or safety factor; or defining exposure or effects. The Agency also reviews as a ''priority'' study any study which was not relied on but which, if considered, arguably would change the outcome of the Agency's risk assessment or regulatory judgement or significantly affect the record underlying the Agency's conclusions. In addition, an Office may selectively review the ethics of any non-priority study, as it deems appropriate.

If a study raises potential ethical concerns or if there is uncertainty, the primary Office consults with the Human Subjects Research Review Official (HSRRO) and they jointly develop an evaluation plan for the study, which may include soliciting outside ethics advice. Senior Agency officials decide the appropriate action to take concerning ethically problematic studies on a case-by-case basis. Depending on the context, senior officials could include senior executives in the program office of concern, the Agency's HSRRO, and/or the Agency Science Advisor. If appropriate, the senior Agency officials may seek independent advice from an external peer review group such as the Science Advisory Board or the FIFRA Scientific Advisory Panel.

## V. Statutory and Executive Order Reviews

Since this Notice does not impose any requirements, and instead describes EPA's current case-by-case approach for reviewing certain human studies, and seeks comments on EPA's plans for amending that process and any suggestions for the Agency to consider in developing a subsequent notice of proposed rulemaking, the various other

review requirements that apply when an agency imposes requirements do not apply to this action.

As part of your comments on this Notice you may include any comments or information that you have regarding these requirements. In particular, any comments or information that would help the Agency to assess the potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note); or to consider environmental health or safety effects on children pursuant to Executive Order 13045, titled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). The Agency will consider such comments during the development of any subsequent notice of proposed rulemaking as it takes appropriate steps to address any applicable requirements.

**List of Subjects**

Environmental protection, Protection of human research subjects.

Dated: February 2, 2005.

**Susan B. Hazen,**

*Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*

[FR Doc. 05–2371 Filed 2–3–05; 11:43 am]

**BILLING CODE 6560–50–S**

## FARM CREDIT ADMINISTRATION

### Farm Credit Administration Board; Regular Meeting; Sunshine Act

**AGENCY:** Farm Credit Administration.

**SUMMARY:** Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the regular meeting of the Farm Credit Administration Board (Board).

**DATE AND TIME:** The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on February 10, 2005, from 9 a.m. until such time as the Board concludes its business.

**FOR FURTHER INFORMATION CONTACT:** Jeanette C. Brinkley, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

**ADDRESSES:** Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090.

**SUPPLEMENTARY INFORMATION:** This meeting of the Board will be open to the public (limited space available). In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:

**Open Session**

*A. Approval of Minutes*

- January 13, 2005 (Open).

*B. New Business—Other*

- Spring Unified Agenda and Regulatory Performance Plan.

Dated: February 3, 2005.

**Jeanette C. Brinkley,**

*Secretary, Farm Credit Administration Board.*

[FR Doc. 05–2541 Filed 2–4–05; 2:26 pm]

**BILLING CODE 6705–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

**[DA 05–311]**

### Permanent Process For Registering Links In The 71–76 GHz, 81–86 GHz, And 92–95 GHz Bands

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice.

**SUMMARY:** The Wireless Telecommunications Bureau (''WTB'' or ''Bureau'') announces additional details of the link registration process for the 71–76, 81–86, 92–94.0 and 94.1–95 GHz bands. This public notice also establishes February 8, 2005, as the date on which the Commission's Universal Licensing System (ULS) will no longer process link registrations and the third party database system will become the sole source for registering links.

**DATES:** Effective February 8, 2005.

**ADDRESSES:** Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Cheryl Black or Stephen Buenzow, Broadband Division, WTB, 717–338–2687 or questions regarding the application filing and link registration procedure outlined in this public notice may be directed to the ULS Hotline at 1–888–CallFCC Option #2.

**SUPPLEMENTARY INFORMATION:** The full text of this Public Notice is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY–A–257, 445 12th Street, SW., Washington, DC 20554. The complete text may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., (BCPI), Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC. The complete item is also available on the Commission's Web site at *http://www.fcc.gov/wtb.*

**Background**

On October 16, 2003, the Commission adopted a Report and Order [1] establishing service rules to promote non-Federal Government development and use of the ''millimeter wave'' spectrum in the 71–76 GHz, 81–86 GHz and 92–95 GHz bands [2] on a shared basis with Federal Government operations.[3] The Commission adopted a flexible and innovative regulatory framework for the 71–95 GHz bands that would not require traditional frequency coordination among non-Federal Government users. Under this approach, the Commission issues an unlimited number of non-exclusive nationwide licenses to non-Federal Government entities for the 12.9 gigahertz of spectrum allocated for commercial use.[4] These licenses serve as a prerequisite for registering individual point-to-point links, which in turn is required prior to operating a link. Furthermore, the 71–95 GHz bands are allocated on a shared basis with Federal Government users. Therefore, a licensee may not operate on a link until the link has been coordinated with the National Telecommunications and Information

[1] In the *Report and Order* released November 4, 2003, the Commission adopted rules for both unlicensed (Part 15) and licensed (Part 101) use of portions of these bands. Allocations and Service Rules for the 71–76 GHz, 81–86 GHz and 92–95 GHz Bands, WT Docket No. 02–146, *Report and Order*, 69 FR 3257, January 23, 2004, 18 FCC Rcd 23318 (2003) (*Report and Order*) (*recon. pending*). The instant Public Notice concerns licensed use of the bands, which involves all of the bands except for 100 megahertz of spectrum at 94.0–94.1 GHz. For convenience only, we refer to the licensed spectrum herein as ''the bands,'' ''the Millimeter Wave 70/80/90 GHz Radio Service,'' or ''71–95 GHz''; such references do not include 94.0–94.1 GHz. *See* note, *infra*.

[2] On February 23, 2004, The Wireless Communications Association International, Inc. filed a petition for reconsideration of certain aspects of the *Report and Order* relating to the 71–76 and 81–86 GHz bands.

[3] In the context of spectrum management, ''Federal Government'' refers to use by the Federal Government and ''non-Federal Government'' refers to use by private entities and state and local governments. *See Report and Order*, 18 FCC Rcd at 23319 n.3. *See also* 47 CFR 101.147(z) (sites may not operate until NTIA approval is received); 101.511 (authorization will be granted upon proper application filing and link coordination in accordance with the Commission's rules); 101.1523 (sharing and coordination among non-Federal Government licensees and between non-Federal Government licensees and Federal Government services).

[4] The 71–76 GHz, 81–86 GHz and 92–95 GHz bands are allocated to both Federal Government and non-Federal Government users on a co-primary basis, except the 94.0–94.1 GHz portion, which is allocated for exclusive Federal Government use. *See generally, Report and Order*, 18 FCC Rcd at 23322–31.