

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8474-1]

Acid Rain Program: Notice of Annual Adjustment Factors for Excess Emission Penalty**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of annual adjustment factors for excess emissions penalty.

SUMMARY: Under the Acid Rain Program, affected units must hold enough allowances to cover their sulfur dioxide emissions and meet an emission limit for nitrogen oxides. Under 40 CFR 77.6, units that do not meet these requirements must pay a penalty without demand to the Administrator based on the number of excess tons emitted times \$2000 as adjusted by an annual adjustment factor that must be published in the **Federal Register**.

The annual adjustment factor for adjusting the penalty for excess emissions of sulfur dioxide and nitrogen oxides under 40 CFR part 77 for compliance year 2007 is 1.6364. This value is derived using the Consumer Price Index ("CPI") for 1990 and 2007 (as defined at 40 CFR part 72, the 2007 CPI is based on the August 2006 CPI for all urban consumers), and corresponds to a penalty of \$3273 per excess ton of sulfur dioxide or nitrogen oxides emitted.

The annual adjustment factor for adjusting the penalty for excess emissions of sulfur dioxide and nitrogen oxides under 40 CFR part 77 for compliance year 2008 is 1.6687. This value is derived using the Consumer Price Index ("CPI") for 1990 and 2008 (as defined at 40 CFR part 72, the 2008 CPI is based on the August 2007 CPI for all urban consumers), and corresponds to a penalty of \$3337 per excess ton of sulfur dioxide or nitrogen oxides emitted.

FOR FURTHER INFORMATION CONTACT: Robert Miller, Clean Air Markets Division (6204), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460 at (202) 343-9077 or miller.robertl@epa.gov.

Dated: September 20, 2007.

Larry F. Kertcher,

Acting Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2007-0942; FRL-8474-4]

Human Studies Review Board; Notice of Public Meeting**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: The U.S. Environmental Protection Agency's (EPA or Agency) Office of the Science Advisor (OSA) announces a public meeting of the Human Studies Review Board (HSRB) to advise the Agency on EPA's scientific and ethical reviews of human subjects' research.

DATES: The public meeting will be held from October 24, 2007 from approximately 8:30 a.m. to approximately 3:30 p.m.; October 25, 2007 from approximately 8 a.m. to approximately 6:30 p.m.; and October 26, 2007 from approximately 8 a.m. to approximately 3 p.m. Eastern Time.

Location: Environmental Protection Agency, Conference Center—Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Drive, Arlington, VA 22202.

Meeting Access: Seating at the meeting will be on a first-come basis. To request accommodation of a disability please contact the person listed under **FOR FURTHER INFORMATION CONTACT** at least 10 business days prior to the meeting, to allow EPA as much time as possible to process your request.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process.

Additional information concerning submission of relevant written or oral comments is provided in Unit I.D. of this notice.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes further information should contact Crystal Rodgers-Jenkins, EPA, Office of the Science Advisor, (8105R), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-5275; fax: (202) 564-2070; e-mail addresses: rodgers-jenkins.crystal@epa.gov. General information concerning the EPA HSRB can be found on the EPA Web site at <http://www.epa.gov/osa/hsrb/>.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2007-0942, by one of the following methods:

Internet: <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

E-mail: ord.docket@epa.gov.

Mail: Environmental Protection Agency, EPA Docket Center (EPA/DC), ORD Docket, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

Hand Delivery: The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Ave., NW., Washington, DC. The hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202) 566-1744 or e-mail the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available on the Web site (<http://www.epa.gov/epahome/dockets.htm>).

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2007-0942. 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.regulations.gov>, 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 <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, 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 <http://www.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.

SUPPLEMENTARY INFORMATION:

I. Public Meeting

A. Does This Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who conduct or assess human studies, especially studies on substances regulated by EPA or to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 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 regulations.gov, you may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the ORD Docket, EPA/DC, Public Reading Room. The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Ave., NW., Washington, DC. The hours of operation are 8:30 a.m. to 4:30 p.m. EST, Monday through Friday, excluding Federal holidays. Please call (202) 566-1744 or e-mail the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available on the Web site (<http://www.epa.gov/epahome/dockets.htm>).

EPA's position paper(s), charge/questions to the HSRB, and the meeting agenda will be available by early October 2007. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, from the

regulations.gov Web site and the EPA HSRB Web site at <http://www.epa.gov/osa/hsrb/>. For questions on document availability or if you do not have access to the Internet, consult the person listed under **FOR FURTHER INFORMATION**. Public comments received on the document titled, "Scientific and Ethical Approaches for Observational Exposure Studies," may be listed under Docket ID No. EPA-HQ-ORD-2007-0972 or Docket ID No. EPA-HQ-ORD-2007-0942.

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

You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide copies of any technical information and/or data you used that support your views.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

D. How May I Participate in This Meeting?

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-ORD-2007-0942 in the subject line on the first page of your request.

a. **Oral comments.** Requests to present oral comments will be accepted up to October 17, 2007. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments at the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via email) to the person listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern time, October 17, 2007 in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Officer (DFO) to review the agenda to provide an appropriate public comment period. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for

audiovisual equipment (e.g., overhead projector, LCD projector, chalkboard). Oral comments before the HSRB are limited to five minutes per individual or organization. Please note that this limit applies to the cumulative time used by all individuals appearing either as part of, or on behalf of an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand these time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, there may be flexibility in time for public comments. Each speaker should bring 25 copies of his or her comments and presentation slides for distribution to the HSRB at the meeting.

b. **Written comments.** Although you may submit written comments at any time, for the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your comments at least five business days prior to the beginning of the meeting. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, October 17, 2007. You should submit your comments using the instructions in Unit I.C. of this notice. In addition, the Agency also requests that person(s) submitting comments directly to the docket also provide a copy of their comments to the person listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

E. Background

A. Topics for Discussion

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. App.29. The HSRB provides advice, information, and recommendations to EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) Research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of

research. The HSRB reports to the EPA Administrator through EPA's Science Advisor.

The October 24–26, 2007 meeting of the Human Studies Review Board will address scientific and ethical issues surrounding:

- Review of EPA draft document *Scientific and Ethical Approaches for Observational Exposure Studies*. The document, prepared by researchers in EPA's National Exposure Research Laboratory, identifies the types of issues that should be considered in planning and implementing observational human exposure studies and provides information and resources to assist EPA researchers in these studies.

- A published report of a completed clinical trial measuring the effects of single and repeated treatments with sodium azide on blood pressure in human subjects. Sodium azide is a pesticidally active ingredient being proposed as a replacement for the fumigant methyl bromide.

- A research proposal from Carroll-Loye Biological Research to evaluate the field efficacy in repelling mosquitoes of three registered products containing picaridin.

- A research proposal from Carroll-Loye Biological Research to evaluate the laboratory efficacy in repelling ticks of three registered products containing picaridin.

- A research proposal from Insect Control & Research, Inc. to evaluate the laboratory efficacy in repelling mosquitoes of the genus *Culex* of two registered products containing picaridin.

- A report of a completed field study by Carroll-Loye Biological Research of the mosquito repellent efficacy of a registered product containing Oil of Lemon Eucalyptus.

- Three closely related product-specific reports from a single completed field study by Carroll-Loye Biological Research of the mosquito repellent efficacy of four pesticides, all containing Deet.

- At the Board's request, discussion on the frequency and duration of exposure of subjects to potential mosquito landings.

In addition, EPA will report to the Board on its consideration of issues relating to the design of sampling strategies for handler research programs proposed by the Agricultural Handlers Exposure Task Force and the Antimicrobials Exposure Assessment Task Force II.

Finally, the Board may also discuss planning for future HSRB meetings.

B. Meeting Minutes and Reports

Minutes of the meeting, summarizing the matters discussed and recommendations, if any, made by the advisory committee regarding such matters will be released within 90 calendar days of the meeting. Such minutes will be available at <http://www.epa.gov/osa/hsrb/> and <http://www.regulations.gov>. In addition, information concerning a Board meeting report, if applicable, can be found at <http://www.epa.gov/osa/hsrb/> or from the person listed under **FOR FURTHER INFORMATION**.

Dated: September 21, 2007.

George Gray,

EPA Science Advisor.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–8474–3]

Notice of Availability of the External Review Draft of a “Framework for Determining a Mutagenic Mode of Action for Carcinogenicity: Using EPA’s 2005 Cancer Guidelines and Supplemental Guidance for Assessing Susceptibility From Early-Life Exposure to Carcinogens”

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Document Availability for Public Comment.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 60-day public comment period for the External Review Draft of the “Framework for Determining a Mutagenic Mode of Action for Carcinogenicity: Using EPA’s 2005 *Cancer Guidelines and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*” (or *Framework*). EPA is releasing this draft document solely for the purpose of seeking public comment prior to external peer review. Following the period for public comment, the document will be reviewed by an external panel of experts. The date and other details about the external review will be published in a separate **Federal Register** notice. EPA will consider both the public and the external peer review comments when revising the draft *Framework*. Members of the public may obtain the draft guidance from <http://www.regulations.gov>; or <http://www.epa.gov/osa/mmoaframework>; or from Dr. Resha Putzrath via the contact information below.

The purpose of the *Framework* is to expand and clarify discussions found in the *Cancer Guidelines and Supplemental Guidance* on characteristics to be evaluated for a chemical’s potential for a mutagenic mode of action (MOA). These documents can be obtained from <http://www.epa.gov/cancerguidelines>. This *Framework* document is not a prescriptive guide on how any particular type of assessment should be conducted within an EPA program or regional office. Rather, it is a science-based document that is intended to help EPA’s risk assessors determine whether data support a finding of a mutagenic MOA for carcinogenicity. It discusses mutagenicity only within the context of a mutagenic MOA for carcinogenicity and not for other adverse endpoints that involve mutations. EPA’s Risk Assessment Forum oversaw the development of this draft document.

EPA’s *Cancer Guidelines* emphasize using MOA information in interpreting and quantifying the potential cancer risk to humans. The *Supplemental Guidance* discusses the use of age-dependent adjustment factors (ADAFs) with the derived cancer slope factors (and appropriate age-specific estimates of exposure) in the development of risk estimates if the weight of evidence supports a mutagenic MOA. This default approach is used only when appropriate chemical-specific data are not available on susceptibility from early-life exposures.

ADDRESSES: The draft document is available electronically through the EPA Office of the Science Advisor’s Web site at: <http://www.epa.gov/osa/mmoaframework>.

FOR FURTHER INFORMATION CONTACT: For more information, contact Dr. Resha Putzrath, Office of the Science Advisor, Mail Code 8105–R, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–3229; fax number: (202) 564–2070, e-mail: putzrath.resha@epa.gov.

SUPPLEMENTARY INFORMATION: In response to requests from numerous stakeholders following EPA’s release of the *Supplemental Guidance* in 2005, the Risk Assessment Forum has prepared a framework document that expands and clarifies characteristics used to determine a chemical’s potential for a mutagenic MOA for carcinogenicity. This determination affects consideration of adjusting cancer potencies via the ADAFs when exposures of these carcinogens occur to children. The *Framework* is meant to complement EPA’s 2005 *Cancer Guidelines and*