inform IRBs about any prior reviews, even if the sponsor or investigator had not sought the prior review, but somehow knew about it. For example, if investigator X and investigator Y were using the same protocol, and if investigator X knew that an IRB had disapproved investigator Y's protocol, should investigator X inform his or her IRB about that disapproval even though it involved a different investigator? If the sponsor knew that an IRB had disapproved investigator Y's protocol, should it notify investigator X so that he or she could inform his or her IRB? FDA invites comment on these issues.

3. Who should receive the disclosures? The OIG report states that IRB's that are reviewing or are going to review a protocol should be informed about prior IRB reviews. This assumes that the prior IRB's decision is known at the time the second IRB is asked to review the protocol. But what happens if the new IRB has already approved the protocol at the time the prior IRB's decision becomes known? Would information about prior IRB reviews still be helpful? One could argue that sponsors and investigators should inform new IRBs about prior IRB reviews, even if the new IRB has already approved the protocol, because the prior reviews might be relevant to the new IRBs continuing review of a protocol.

4. What information should be disclosed? The type of information to be disclosed depends on the purpose of the disclosure. If the purpose is solely to be certain that an IRB is aware of a prior adverse conclusion, perhaps only unfavorable prior reviews would need to be disclosed. If the purpose of the disclosure is to ensure that IRBs receive all relevant information about a study, it might be appropriate to disclose all prior IRB decisions, both positive and negative. Should all prior IRB reviews, including approvals, be disclosed?

5. If a proposal would not require disclosure of all prior IRB decisions, what information should be disclosed? Even if the purpose of disclosure is solely to be sure an IRB is aware of an unfavorable IRB review, there could be different degrees of disclosure. An unfavorable IRB decision could encompass complete disapproval of a protocol, a decision to approve a protocol with stipulations, and a request for significant changes to a protocol. Even a decision to require additional reviews by the IRB could be considered as an unfavorable decision.

A requirement to disclose only prior unfavorable IRB reviews may presume that an unfavorable review is more likely to be correct than a favorable review. If one presumes that the earlier IRB correctly disapproved, or requested modifications of, a protocol, then a new IRB could, indeed, benefit from knowing about that decision. This could be the case, for example, if the earlier IRB disapproved a protocol because one of its scientific members recognized that the investigational product would present a greater risk of harm to research subjects than was acknowledged in the informed consent document, based on that member's knowledge of certain animal studies. This information would be helpful to a new IRB, particularly if its scientific members did not possess the same expertise as the earlier IRB. On the other hand, a favorable decision by a prior IRB with superior expertise in a particular case could also be of value to a subsequent IRB as well.

Conversely, in cases where an initial review, either favorable or unfavorable, was not well-founded, information about the earlier IRB's review decision may offer little or no value to a new IRB and might lead to an ill-considered, ''defensive'' acceptance or rejection of a satisfactory proposal. For example, if an IRB was associated with an institution, and the institution was well-known or had a good reputation, a subsequent IRB might be inclined to follow the first IRB's decision even if the first IRB's decision was not well-founded.

6. To permit a subsequent IRB to assess the value of a prior IRB decision, should information about the basis for the prior decision be disclosed? Currently, IRBs are not generally required to document the reasons for approving a study, so if a proposed rule would require all IRB decisions to be disclosed, IRBs might have to explain their reasons for approving a study. Should the disclosed information include information about the composition and expertise of the prior IRB's members? What would be the additional burden on IRBs if FDA required the disclosure of the basis for all or even some IRB review decisions? How would this affect the time needed to conduct an IRB review?

7. How should FDA enforce the requirement? The OIG report did not suggest any method for enforcing a requirement that these disclosures about prior IRB reviews occur. What would be an appropriate sanction to impose on an investigator or sponsor for failure to comply with a disclosure requirement?

FDA must learn about a violation before it can consider what sanctions might be imposed. The OIG report did not recommend that sponsors and investigators inform FDA about any prior IRB reviews; it only recommended that sponsors and investigators inform IRBs. If FDA has no knowledge about the prior IRB review, the agency might find it difficult to detect noncompliance. FDA invites comment on how it might enforce the requirement efficiently.

8. Are There Other Ways to Deal with IRB Shopping Other Than Disclosure of Prior IRB Reviews? Although the OIG report recommended requiring disclosure of prior IRB reviews, there may be other ways to deal with IRB shopping. Therefore, if the problem of IRB shopping is significant enough to warrant Federal regulatory action, are there other requirements that could be employed to address the problem besides mandating disclosure of prior IRB reviews?

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the issues presented in this ANPRM by June 4, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 23, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–5247 Filed 3–5–02; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WI104–01–7334; FRL–7153–8]

Approval and Promulgation of Air Quality Implementation Plans; Wisconsin; Excess Volatile Organic Compound Emissions Fee Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a rule that revises Wisconsin's State Implementation Plan (SIP) for ozone. The rule requires major stationary sources of volatile organic compounds (VOC) in the Milwaukee nonattainment area to pay a fee to the state if the area fails to attain the one-hour national ambient air quality standard for ozone by 2007. The fee must be paid beginning in 2008 and in each calendar year thereafter, until the

area is redesignated to attainment of the one-hour ozone standard. Wisconsin submitted this rule on December 22, 2000, as part of the state's demonstration of attainment for the one-hour ozone standard.

DATES: EPA must receive comments on this proposed action by April 5, 2002.

ADDRESSES: Send written comments to: Carlton T. Nash, Chief, Regulation Development Section, Air Programs Branch (AR–18J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the proposed SIP revision and EPA's analysis are available for inspection at the following location: United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Kathleen D'Agostino at (312) 886–1767 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Regulation Development Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767.

SUPPLEMENTARY INFORMATION:

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I. What Action Is EPA Taking?

The EPA is proposing to approve a rule that revises Wisconsin's ozone SIP. The rule requires major stationary sources of VOC in the Milwaukee nonattainment area to pay a fee to the state if the area fails to attain the one-hour national ambient air quality standard for ozone by 2007. The fee must be paid beginning in 2008 and in each calendar year thereafter, until the area is redesignated to attainment of the 1-hour ozone standard.

The EPA is proposing to approve this rule because it is consistent with the requirements of the Clean Air Act (Act).

II. Who Has To Pay These Fees?

This rule applies to major stationary VOC sources located in the Milwaukee nonattainment area. This area includes Kenosha, Milwaukee, Ozaukee, Racine, Washington, and Waukesha Counties. For this area, major sources are defined as those for which the maximum theoretical emissions are 25 tons of VOC per year or more.

III. How Are the Fees Calculated?

The fee is initially set at $5,000 per ton of VOCs emitted by the source during the previous calendar year in excess of 80% of the baseline amount. The fee is to be adjusted annually, beginning in 1990, by the percentage by which the consumer price index has been adjusted. The baseline is the lower of the source's actual or allowable VOC emissions, during calendar year 2007. The fee is waived during any year that is treated as an extension year, as provided by section 181(a)(5) of the Act.

IV. Is Wisconsin Required To Adopt an Excess Emission Fee Rule?

Under sections 182(d)(3), (e), and 185 of the Act (the Act), states are required to adopt an excess emissions fee regulation for ozone nonattainment areas classified as severe or extreme. This regulation requires major stationary sources of VOC in the nonattainment area to pay a fee to the state if the area fails to attain the standard by the attainment date set forth in the Act. In Wisconsin, the Milwaukee nonattainment area is classified as severe.

Section 182(f) of the Act requires states to apply the same requirements to major stationary sources of oxides of nitrogen (NO_X) as are applied to major stationary sources of VOC. However, section 182(f) also allows the EPA to grant a waiver from this requirement if additional NO_X reductions would not contribute to attainment of the national ambient air quality standard for ozone or if they would not produce ozone air quality benefits. On July 13, 1994, the states of Wisconsin, Illinois, Indiana and Michigan jointly petitioned for an exemption from the requirements of section 182(f). EPA granted the waiver on January 26, 1996. The waiver was revised on November 13, 2001, when EPA published a final approval of the Wisconsin's demonstration of attainment of the one-hour ozone standard for the Milwaukee-Racine area. This revision changed the basis for the waiver from ''would not contribute to (or might interfere with) attainment'' to additional NO_X reductions beyond those submitted by the state are ''excess reductions'' and are not required for attainment of the ozone standard. Also the waiver was modified to no longer apply to the motor vehicle inspection and maintenance (I/M) program. However, while the basis for the NO_X waiver was changed, the effect of the waiver on NO_X related requirements (with the exception of the I/M program) remains unchanged. For example the waiver from RACT for major NO_X sources, offsets for major new sources, and Lowest Achievable Emission Rate Technology for major new sources remains unaffected. Therefore, because an approved section 182(f) waiver remains in effect, Wisconsin is not required to include major sources of NO_X in its excess emissions fee rule.

V. What Administrative Requirements Did EPA Consider?

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain an unfunded mandate, nor does it significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This proposed rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to approve a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTA), 15 U.S.C. 272 note, requires federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impracticable. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a SIP submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a SIP submission that otherwise satisfies the provisions of the Act. Therefore, the requirements of section 12(d) of the NTTA do not apply.

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order, and has determined that the rule's requirements do not constitute a taking. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Nitrogen dioxide, Ozone, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: February 15, 2002.

Bertram C. Frey,

Acting Regional Administrator, Region 5.

[FR Doc. 02–5311 Filed 3–5–02; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH 31

Endangered and Threatened Wildlife and Plants; Reopening of Public Comment Period and Notice of Availability of Draft Economic Analysis for Proposed Critical Habitat Determination for the Carolina Heelsplitter

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of reopening of public comment period and availability of draft economic analysis.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of the draft economic analysis for the proposed designation of critical habitat for the Carolina heelsplitter (*Lasmigona decorata*). We also provide notice that the public comment period for the proposal is reopened to allow all interested parties to submit written comments on the proposal and the draft economic analysis. Comments previously submitted during the comment period need not be resubmitted as they will be incorporated into the public record and will be fully considered in the final determination on the proposal.

DATES: The original comment period closed on September 10, 2001. The comment period is hereby reopened until April 5, 2002. We must receive comments from all interested parties by the closing date. Any comments that we receive after the closing date will not be considered in the final decision on this proposal.

ADDRESSES: Copies of the draft economic analysis can be obtained by writing to or calling the State Supervisor, Asheville Field Office, U.S. Fish and Wildlife Service, 160 Zillicoa Street, Asheville, North Carolina 28801; telephone 828/258–3939.

If you wish to comment, you may submit your comments by any one of several methods:

1. You may submit written comments and information to the State Supervisor, Asheville Field Office, U.S. Fish and Wildlife Service, 160 Zillicoa Street, Asheville, North Carolina 28801.

2. You may hand-deliver written comments to our Asheville Field Office, at the above address or fax your comments to 828/258–5330.

Comments and materials received, as well as supporting documentation used in preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: John A. Fridell, Fish and Wildlife Biologist (see **ADDRESSES** section).

SUPPLEMENTARY INFORMATION:

Background

The Carolina heelsplitter is a medium sized freshwater mussel, reaching up to about 114.8 millimeters (4.6 inches in length), with a greenish brown to dark brown shell (Keferl 1991). It currently has a very fragmented, relict distribution but historically was known from several locations within the Catawba and Pee Dee River systems in North Carolina and the Pee Dee and Savannah River systems, and possibly the Saluda River system, in South Carolina (Clarke 1985, Keferl and Shelly 1988, Keferl 1991). Recent collection records (Keferl and Shelly 1988; Keferl 1991; Alderman 1995, 1998a, and 1998b; North Carolina Wildlife Resources Commission 1999 and 2000) indicate that the Carolina heelsplitter has been eliminated from the majority of its historical range, and only six populations of the species are known to exist. In Union County, North Carolina, one small remnant population occurs in Waxhaw Creek, a tributary to the Catawba River, and another small population occurs in both Goose Creek, a tributary in the Rocky River, and Duck Creek, a tributary to Goose Creek, in the Pee Dee River system. In South Carolina, there are four small surviving populations—one each in the Pee Dee and Catawba River systems and two in the Savannah River system. The population in the Pee Dee River system occurs in a relatively short reach of the Lynches River in Chesterfield, Lancaster, and Kershaw Counties and extends into Flat Creek, a tributary to the Lynches River in Lancaster County. In the Catawba River system, the species survives only in a short reach of Gills Creek in Lancaster County. In the Savannah River system, one population is found in Turkey Creek in Edgefield and McCormick Counties, and two of its tributaries, Mountain Creek and Beaverdam Creek in Edgefield County; and another smaller population survives in Cuffytown Creek, in Greenwood and McCormick Counties. Despite extensive surveys, no evidence of a surviving population has been found in recent years in the Saluda River system (Keferl and Shelly 1988; Keferl 1991; Alderman 1998a). Several factors adversely affecting the water and habitat quality of our creeks and rivers are believed to