drug application from the drug sponsor, and has not established and codified a tolerance level for the drug, the use of such drugs is illegal.

FDA has not evaluated the safety of growth promoting implants in non-ruminating young calves. Therefore, FSIS cannot determine when the edible tissues from animals to whom such substances have been administered are not unfit for human food. If FSIS cannot make this determination, it cannot determine when the edible product from those animals that have been administered the unapproved new animal drug are not adulterated, and thus it cannot apply the mark of inspection to such products.

HACCP Systems

9 CFR 417.2(a) requires establishments to conduct a hazard analysis to determine what food safety hazards are reasonably likely to occur in their process and to identify the preventive measures that the establishment can apply to control those hazards. The hazards may occur before, during, or after entry into the establishment. FSIS has identified drug residues as possible food safety hazards (9 CFR 417.2(a)(3)).

Section 417.2(a)(1) states that a food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish control measures because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. Whenever a hazard analysis reveals that one or more hazards are reasonably likely to occur in the production process, the regulations require that the establishment develop and implement a written HACCP plan that includes specific control measures for each hazard so identified (417.2(b)(1) and (c)).

Requirement and Basis for Reassessment

Section 417.4(a)(3) states that every establishment shall reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. The finding that new animal drugs have been knowingly administered, on a widespread basis, to a production class of animals in which their use is not approved, represents information that could alter the hazard analysis, and ultimately the HACCP plan, of any establishment that slaughters animals of that class, in this case young calves, for human food. Therefore, establishments that slaughter young calves, including those young calves marketed, slaughtered, and labeled as ''veal,'' need to consider the hazard presented by the illegal use of animal drugs in the animals they slaughter, and what actions they should take to control it if they determine that it is reasonably likely to occur, as a result of their reassessments.

If reassessment results in a determination by the establishment that a residue of an unapproved new animal drug is a food safety hazard that is reasonably likely to occur, this hazard must be addressed in the establishment's HACCP plan. However, FSIS recognizes that some slaughterers employ measures to ensure that they do not purchase food animals for slaughter with violative animal drug residues. These slaughterers should consider incorporating these measures into their HACCP plans or prerequisite programs.

FSIS Actions To Enforce and Facilitate Compliance With the Reassessment

The Agency intends to instruct inspection program personnel to verify, as part of the Agency's verification of the 2005 hazard analysis reassessment, that establishments that slaughter young calves have considered the hazard of illegal residues. Before performing that verification, inspection program personnel will ensure that all establishments that slaughter young calves are aware that the Agency has issued this notice. They will also ensure that those establishments that have not yet reassessed their HACCP plans, based on the relevant FSIS findings discussed earlier, begin their reassessment. By looking into establishments' reassessment actions before the time that the establishments are required to complete their reassessments, FSIS will ensure that all establishments slaughtering young calves, including establishments that are considered small and very small businesses, and those that may not belong to a trade association, are aware of this notice.

Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this notice in accordance with the Paperwork Reduction Act and has determined that the paperwork requirements for the regulations that require establishments that slaughter calves to reassess their HACCP Plans have already been accounted for in the Pathogen Reduction/HACCP Systems information collection approved by the Office of Management Budget (OMB). The OMB approval number for the Pathogen Reduction/HACCP Systems information collection is 0583–0103.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page.

Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

Done at Washington, DC, on December 20, 2004.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 04–28083 Filed 12–22–04; 8:45 am]

BILLING CODE 3410–DM–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–MI–0002; FRL–7849–2]

Approval and Promulgation of Implementation Plans: Michigan: Oxides of Nitrogen

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is approving a revision to the plan prepared by Michigan that will limit the emissions of oxides of nitrogen (NO_X) from large stationary sources (*i.e.* power plants, industrial boilers and cement kilns). This plan meets all of the requirements contained in an EPA rule that was published in the **Federal Register** on April 16, 2004. This rule, otherwise known as the NO_X SIP Call Phase I provides for NO_X reductions from

sources in 20 States in the eastern half of the country. The effect of this approval is to ensure federal enforceability of the state air program plan and to maintain consistency between the state-adopted plan and the approved State Implementation Plan (SIP).

DATES: Written comments must be received on or before January 24, 2005.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2004–MI–0002 by one of the following methods: Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

Agency Web site: http://docket.epa.gov/rmepub/index.jsp. Regional Material in EDocket (RME), EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

E-mail: bortzer.jay@epa.gov.

Fax: (312) 886–5824.

Mail: You may send written comments to: J. Elmer Bortzer, Chief, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand delivery: Deliver your comments to: J. Elmer Bortzer, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604.

Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Regional Material in EDocket (RME) ID No. R05–OAR–2004–MI–0002. EPA's policy is that all comments received will be included in the public docket without change, 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 Regional Material in EDocket (RME), regulations.gov, or e-mail. The EPA Regional Material in EDocket (RME) Web site and the federal regulations.gov Web site 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 RME 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 instructions on submitting comments, go to Section I of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the electronic docket are listed in the Regional Material in EDocket (RME) index at *http://www.epa.gov/rmepub/index.jsp.* Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. Please telephone Douglas Aburano at (312) 353–6960 before visiting the Region 5 Office.

FOR FURTHER INFORMATION CONTACT: Douglas Aburano, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), USEPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6960. *aburano.douglas@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

This action applies to large stationary sources of NO_X (such as electric generating units that produce electricity for sale, other large boilers that produce steam and/or electricity but do not sell electricity, and cement kilns) in the southern counties (Allegan, Barry, Bay, Berrien, Branch, Calhoun, Cass, Clinton, Eaton, Genesee, Gratiot, Hillsdale, Ingham, Ionia, Isabella, Jackson, Kalamazoo, Kent, Lapeer, Lenawee, Livingston, Macomb, Mecosta, Midland, Monroe, Montcalm, Muskegon, Newaygo, Oakland, Oceana, Ottawa, Saginaw, Saint Clair, Saint Joseph, Sanilac, Shiawassee, Tuscola, Van Buren, Washtenaw, Wayne) of Michigan. This action also applies to the unit at DTE Energy's Harbor Beach facility in Huron County.

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

1. *Submitting CBI.* Do not submit Confidential Business Information (CBI) to EPA through Regional Material in EDocket (RME), 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:

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

b. 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.

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

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

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

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

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

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

II. What Action Is EPA Taking Today?

EPA is proposing to approve the NO_X SIP submitted on April 3, 2003 as modified on May 27, 2004. EPA finds that Michigan's submittals are fully approvable because the initial April 3, 2003 submittal was conditionally approved and the conditions for full approvability were met in the May 27, 2004 submittal. In combination, these two submittals meet the requirements of the Phase I NO_X SIP Call.

We are proposing to approve Michigan's revision of the ozone SIP that responds to EPA's Phase I NO_X SIP Call. This revision consists of Michigan Air Pollution Control Rules 803, 805–810, and 812–817 as submitted on April 3, 2003 and Michigan Air Pollution Control Rules 802, 804 and 811 as submitted May 27, 2004. A combined package of these rules 802–817 as submitted on April 3, 2003 and May 27, 2004 was submitted as a supplement to the May 27, 2004 submittal for ease of incorporation by reference. This supplemental submittal was sent by MDEQ to EPA on August 5, 2004.

By this action, we are also proposing to vacate our April 16, 2004 (69 FR 20548) conditional approval of Michigan's earlier NO_X SIP submittal.

III. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

For additional information, see the Direct Final Rule which is located in the Rules section of this **Federal Register**. Copies of the request and the EPA's analysis are available electronically at Regional Material in EDocket (RME) or in hard copy at the above address. Please telephone Douglas Aburano at (312) 353–6960 before visiting the Region 5 Office.

Dated: December 3, 2004.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 04–27984 Filed 12–22–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R03–OAR–2004–DC–0008; FRL–7852–7]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; VOC Emission Standards for Mobile Equipment Repair and Refinishing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the District of Columbia establishing regulations for the control of volatile organic compound (VOC) emissions from mobile equipment repair and refinishing operations in the District of Columbia. In the Final Rules section of this **Federal Register**, EPA is approving the District's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by January 24, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03–OAR–2004–DC–0008 by one of the following methods:

A. Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. Agency Web site: *http://www.docket.epa.gov/rmepub/* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. E-mail: *morris.makeba@epa.gov.*

D. Mail: R03–OAR–2004–DC–0008, Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. Hand Delivery: At the previously-listed EPA Region III address. 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 RME ID No. R03–OAR–2004–DC–0008. 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.docket.epa.gov/rmepub/*, 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 RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are 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 RME 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.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/.* 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 RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the District of Columbia Department of Public Health, Air