the shipping packages or, if the exported product does not have a shipping package or container, on shipping invoices or other documents accompanying the exported product; and

(4) Records demonstrating that the product is not sold or offered for sale in the United States: This may consist of production and shipping records for the exported product and promotional materials.

(c) *Additional recordkeeping requirements for partially processed biological products exported under section 351(h) of the Public Health Service Act.* In addition to the requirements in paragraph (b) of this section, persons exporting a partially processed biological product under section 351(h) of the Public Health Service Act shall maintain, for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, and make available to FDA, upon request, during an inspection for review and copying by FDA, the following records:

(1) Records demonstrating that the product for export is a partially processed biological product and not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) Records demonstrating that the partially processed biological product was manufactured in conformity with current good manufacturing practice requirements;

(3) Records demonstrating the distribution of the exported partially processed biological products; and

(4) Copies of all labeling that accompanies the exported partially processed biological product and other records demonstrating that the exported partially processed biological product is intended for further manufacture into a final dosage form outside the United States; this may include a container label with the statement, ''Caution: For Further Manufacturing Use Only'' and any package insert.

(d) *Notification requirements for drugs, biological products, and devices exported under section 802 of the act.* (1) Persons exporting a human drug, biological product, or device under section 802 of the act, other than a drug, biological product, or device for investigational use exported under section 802(c) of the act, or a drug, biological product, or device exported in anticipation of marketing authorization under section 802(d) of the act, shall provide written notification to FDA. The notification shall identify:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) If the export is to a country not listed in section 802(b)(1) of the act, the country that is to receive the exported article. The notification may, but is not required to, identify countries listed in section 802(b)(1) of the act or state that the export is intended for a listed country without identifying the listed country.

(2) The notification shall be sent to the following addresses:

(i) For biological products and devices regulated by the Center for Biologics Evaluation and Research—Division of Case Management (HFM–610), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852–1448;

(ii) For human drug products—Division of Labeling and Nonprescription Drug Compliance (HFD–310), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737;

(iii) For devices—Division of Program Operations (HFZ–305), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act.* (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biological products, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's trade name;

(ii) If the product is a drug or biological product, the product's abbreviated or proper name or, if the product is a device, the type of device;

(iii) If the product is a drug or biological product, a description of its strength and dosage form and the product's lot or control number or, if the product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported or manufactured, and be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

Dated: March 1, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

Dated: April 10, 2001.[1]

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–31026 Filed 12–18–01; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[KS 0145–1145a; FRL–7120–2]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Control of Emissions From Hospital/Medical/Infectious Waste Incinerators; State of Kansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a revision to the state of Kansas' section 111(d) plan for controlling emissions from existing hospital/medical/infectious waste incinerators. The state revised its existing plan to establish increments of progress and a new compliance date for two HMIWI sources. Approval of the revised state plan will ensure that these requirements are Federally enforceable.

DATES: This direct final rule will be effective February 19, 2002. unless EPA receives adverse comments by January 18, 2002. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to Wayne Kaiser, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Copies of documents relative to this action are available for public inspection during normal business

[1] **Editorial Note:** This document was received at the Office of the Federal Register on December 12, 2001.

hours at the above-listed Region 7 location. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Wayne Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Information regarding this action is presented in the following order:

What Is a 111(d) Plan?

Section 111(d) of the Clean Air Act (CAA) requires states to submit plans to control certain pollutants (designated pollutants) at existing facilities (designated facilities) whenever standards of performance have been established under section 111(b) for new sources of the same type, and EPA has established emission guidelines (EG) for such existing sources. A designated pollutant is any pollutant for which no air quality criteria have been issued, and which is not included on a list published under section 108(a) or section 112(b)(1)(A) of the CAA, but emissions of which are subject to a standard of performance for new stationary sources.

What Are the Regulatory Requirements for HMIWIs?

Standards and guidelines for new and existing HMIWIs were promulgated under the authority of sections 111 and 129 of the CAA on September 15, 1997 (62 FR 48374). These standards are 40 CFR part 60, subpart Ec for new sources, and 40 CFR part 60, subpart Ce for existing sources.

The subpart Ce EG is not a direct Federal regulation but is a ''guideline'' for states to use in regulating existing HMIWIs. The EG requires states to submit for EPA approval a section 111(d) state plan containing air emission regulations and compliance schedules for existing HMIWIs.

What Changes Did the State Make to Its 111(d) Plan?

We originally approved the state's HMIWI 111(d) plan on July 14, 2000 (65 FR 43702), and it became effective on September 12, 2000. Sources were required to be in compliance within one year of the effective date of EPA approval of the state plan, i.e., September 12, 2001, or in any case no later than September 15, 2002. Sources may petition the state for a compliance date extension beyond September 12, 2001, if they are planning to install air pollution control equipment and if they commit to an increment of progress schedule. The final compliance date cannot extend beyond September 15, 2002, however.

Two HMIWIs in Kansas, one each located in Johnson and Wyandotte Counties, requested that they be granted until September 15, 2002, or an additional year, to come into compliance. Both sources justified the need for additional time in order to install air pollution control equipment and related operating and monitoring equipment. The state has approved these requests.

The state has included increments of progress dates in the sources' compliance schedules. Dates have been established for: award of contracts, commence on-site construction, complete initial startup, calibration and adjustment, conduct required performance testing, and demonstrate final compliance. The final compliance date is September 15, 2002.

These compliance extensions constitute a revision to the compliance date that was contained in the approved 111(d) plan. Thus, the state has submitted the new compliance schedules for these two sources to us for approval as an amendment to its 111(d) plan.

This action will ensure consistency between the state plan and the approved Federal plan, and ensure Federal enforceability of the approved state plan.

What Action Are We Taking in This Action?

We are approving these revisions to the state's HMIWI 111(d) plan. We are processing this action as a final action because the revisions make routine changes to the existing plan which are noncontroversial. Therefore, we do not anticipate any adverse comments. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this 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 action merely approves a state action as meeting Federal requirements and imposes no additional requirements. Accordingly, the Administrator certifies that this 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 approves a state action and does not impose any additional enforceable duty, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). For the same reason, this rule also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not 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 approves a state action relating to a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing state plan submissions, our role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), we have no authority to disapprove state submissions for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews state submissions, to use VCS in place of state submissions that otherwise satisfy the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, we have 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. This 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.*).

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. We will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 19, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects 40 CFR Part 62

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Lead, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: December 7, 2001.

James B. Gulliford,

Region Administrator, Region 7.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart R—Kansas

2. Section 62.4179 is amended by adding paragraph (d) to read as follows:

§ 62.4179 Identification of plan.

* * * * *

(d) Amended plan for the control of air emissions from hospital/medical/infectious waste incinerators submitted by the Kansas Department of Health and Environment on October 25, 2001. This plan revision establishes a final compliance date of September 15, 2002, for two incinerators in Johnson and Wyandotte Counties, Kansas. The effective date of the amended plan is February 19, 2002.

[FR Doc. 01–31238 Filed 12–18–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301179A; FRL–6814–4]

RIN 2070–AB78

Sethoxydim; Pesticide Tolerance Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of October 10, 2001, establishing time-limited tolerances for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide). Inadvertently the regulatory text showed the maximum permissible level for residues of sethoxydim in or on ''Sheep, mbyp'' at ''0.5 ppm''. This document makes a technical correction to the regulatory text of the tolerance regulation in 40 CFR 180.412(b) to correctly show the maximum permissible level for residues of sethoxydim in or on ''Sheep, mbyp'' at ''1.0 ppm''.

DATES: This regulation is effective December 19, 2001. Objections and request for hearings, identified by docket control number OPP–301179A, must be received by EPA on or before February 19, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method provided in Adverse comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit II. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–301179A in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9364; e-mail address: pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://