

analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Barbesgaard, P., H. P. Heldt-Hansen, and B. Diderichsen, "On the Safety of *Aspergillus oryzae*: A Review," *Applied Microbiology and Biotechnology*, 36:569-572, 1992.
2. "Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification," *Regulatory Toxicology and Pharmacology*, 12 (3):S114-S128, 1990.
3. Memorandum from J. Madden, FDA, to D. Keefe, FDA, April 11, 1994.
4. Gray, W. D., *The Use of Fungi as Food and in Food Processing*, pp. 42-100, CRC Press, Cleveland, OH, 1970.
5. Joint FAO/WHO Expert Committee on Food Additives. "Toxicological Evaluation of Certain Food Additives," 31st Meeting, Geneva, February 16-25, 1987.
6. Memorandum from H. C. A. Chang, FDA, to D. Keefe, FDA, March 14, 1994.
7. Shipper, M. A. A., "On the Genera *Rhizomucor* and *Parasitella*," *Studies in Mycology*, 17:53-65, 1978.
8. Cristensen, T. et al., "High Level Expression of Recombinant Genes in *Aspergillus oryzae*," *Bio/Technology*, 6:1419-1422, 1988.
9. Herrman, J. L. et al., "Bacterial Glycoproteins: A Link Between Glycosylation and Proteolytic Cleavage of a 19 kDa Antigen from *Mycobacterium tuberculosis*," *EMBO Journal*, 15:3547-3554, 1996.
10. Grinna, L. S., and J. F. Tschopp, "Size Distribution and General Structural Features of N-linked Oligosaccharides from the Methylotrophic Yeast, *Pichia pastoris*," *Yeast*, 5 (2):107-115, 1989.
11. Memorandum from S. E. Carberry, FDA, to D. Keefe, FDA, January 5, 1995.
12. Memorandum from H. C. A. Chang, FDA, to D. Keefe, FDA, February 6, 1995.
13. Memorandum from T. A. Cebula, FDA, to D. Keefe, FDA, April 4, 1995.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.150 is amended by adding paragraph (a)(5) to read as follows:

§ 173.150 Milk-clotting enzymes, microbial.

* * * * *

(a) * * *

(5) *Aspergillus oryzae* modified by recombinant deoxyribonucleic (DNA) techniques to contain the gene coding for aspartic proteinase from *Rhizomucor miehei* var. *Cooney et Emerson* as defined in paragraph (a)(4) of this section, and classified as follows: Class, Blastodeuteromycetes (Hyphomycetes); order, Phialidales (Moniliales); genus, *Aspergillus*; species *oryzae*.

Dated: October 20, 1997.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 97-29048 Filed 10-31-97; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 083-0053a; FRL-5911-4]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Diego County Air Pollution Control District, Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan (SIP). These revisions concern rules from the San Diego County Air Pollution Control District (SDCAPCD) and the Ventura County Air Pollution Control District (VCAPCD). This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act,

as amended in 1990 (CAA or the Act). The revised rules control VOC emissions from metal container, metal closure, and metal coil coating operations and marine vessel coating operations. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

DATES: This action is effective on January 2, 1998 unless adverse or critical comments are received by December 3, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments must be submitted to Andrew Steckel at the Region IX office listed below. Copies of the rule revisions and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:

Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 "M" Street, S.W., Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 92123-1095

San Diego County Air Pollution Control District, 9150 Chesapeake Drive, San Diego, CA 92123-1096

Ventura County Air Pollution Control District, 702 County Square Drive, Ventura, California 93003.

FOR FURTHER INFORMATION CONTACT: Jerald S. Wamsley, Rulemaking Office, AIR-4, Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1226

SUPPLEMENTARY INFORMATION:

I. Applicability

The rules being approved into the California SIP include SDCAPCD's Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations, and VCAPCD's Rule 74.24, Marine Vessel Coating Operations. These rules were submitted by the California Air Resources Board (CARB) to EPA on October 18, 1996 and May 24, 1994, respectively.

II. Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included San Diego and Ventura counties, see 43 FR 8964, 40 CFR 81.305. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the San Diego and Ventura county portions of the California SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Pub. L. 101-549, 104 Stat. 2399, codified at 42 U.S.C. 7401-7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amendment guidance.¹ EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. San Diego County is classified as "serious" and Ventura County as "severe".² As a result, these areas were subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The State of California submitted many revised RACT rules for incorporation into its SIP on October 18, 1996 and May 24, 1994, including the rules being acted on in this document. This document addresses EPA's direct-final action on SDCAPCD's Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations, and VCAPCD's Rule 74.24, Marine Vessel

Coating Operations. SDCAPCD adopted revisions to Rule 67.4 on July 25, 1995 and May 15, 1996. This submitted rule was found to be complete on December 19, 1996 pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51 Appendix V.³ VCAPCD adopted Rule 74.24 on March 8, 1994. EPA found this submitted rule complete on July 14, 1994.

EPA's review of SDCAPCD Rule 67.4 addresses two adopted revisions of the rule, one from July 25, 1995 and May 15, 1996. These two adopted versions of SDCAPCD 67.4 were submitted by CARB to EPA on October 18, 1996. Because the July 25, 1995 revisions to Rule 67.4 are reflected in the later May 15, 1996 revision and adoption, this rulemaking concerns substantively the latest adopted submittal of Rule 67.4, the May 15, 1996 rule revision.

SDCAPCD Rule 67.4 and VCAPCD Rule 74.24 are prohibitory rules governing the use and application of coating compounds containing photochemically reactive volatile organic compounds (VOCs) in their respective industries, metal container, closure, and coil manufacturing and marine vessel building, painting, and repair. VOCs contribute to the production of ground level ozone and smog. These rules were originally adopted as part of both the SDCAPCD and VCAPCD's respective efforts to achieve the National Ambient Air Quality Standard (NAAQS) for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement. EPA's evaluation and final action for these rules follow below.

III. EPA Evaluation and Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 1. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting state and local agencies in developing RACT

rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to "fix-up" their RACT rules. See section 182(a)(2)(A). The CTGs applicable to these rules are as follows: "Control of Volatile Organic Emissions from Existing Stationary Sources Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light Duty Trucks," USEPA, May 1977, EPA-450/2-77-008; and, "Control Technique Guidelines (CTG) for Shipbuilding and Ship Repair Operations (Surface Coating), USEPA, 61 FR 44050-44057, August 27, 1996. Further interpretations of EPA policy are found in the Blue Book, referred to in footnote one. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

On May 2, 1995, EPA approved into the SIP a version of SDCAPCD's Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations, that had been adopted by SDCAPCD on September 27, 1994. The revised version of SDCAPCD Rule 67.4 under consideration today includes the following significant changes from the current SIP rule:

- Lowered VOC limits for end sealing compound for food and beverage containers, from 440 grams/liter (gr/l) to 20 gr/l;
- Added VOC limits for exterior and interior spray coating of new (as opposed to reconditioned) drums, pails, and lids at 340 and 420 gr/l;
- Added requirements for equipment cleaning operations;
- Exempted the use of cleaning material in quantities of less than 10 gallons per month from the prohibition of VOC containing materials;
- Updated several definitions;
- Updated and added test methods; and,
- Revised the exempt compound definition to reference Rule 2, a rule defining exempt compounds for all rules regulating VOC emissions.

EPA has reviewed and approved Rule 2 and similar changes to other VOC related rules for incorporation into the California SIP (see 62 FR 14659, March 27, 1997.)

EPA has evaluated SDCAPCD Rule 67.4 and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore,

¹ Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 Federal Register Notice" (Blue Book) (notice of availability was published in the Federal Register on May 25, 1988); and the existing control technique guidelines (CTGs).

² Both San Diego and Ventura counties retained their designation of nonattainment and were classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 56 FR 56694 (November 6, 1991).

³ EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

SDCAPCD's Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations, is approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

There is no version of VCAPCD's Rule 74.24, Marine Vessel Coating Operations, in the SIP. The submitted rule includes the following provisions: applicability, general and specialty coating emission limits, add-on emission control equipment requirements; allowable exemptions from the rule, recordkeeping requirements, appropriate test methods, violations under the rule, and a list of definitions operable within the rule.

EPA has evaluated VCAPCD Rule 74.24 as submitted and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, VCPCD's Rule 74.24, Marine Vessel Coating Operations, is approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

EPA is publishing this document without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective January 2, 1998, unless, by December 3, 1997, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective January 2, 1998.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of \$100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the

private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a "major" rule as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 2, 1998. 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 in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: September 26, 1997.

Felicia Marcus,
Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(197)(i)(D) and (c)(241)(i)(A)(2) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(197) * * *

(i) * * *

(D) Ventura County Air Pollution Control District.

(1) Rule 74.24, adopted on March 8, 1994.

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(241) * * *

(i) * * *

(A) * * *

(2) Rule 67.4, revised on May 15, 1996.

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[FR Doc. 97-29050 Filed 10-31-97; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 260**

[FRL-5916-3]

Project XL Site-Specific Rulemaking for Molex, Inc., 700 Kingbird Road Facility, Lincoln, NE

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is proposing to implement a project under the Project XL program for the Molex, Inc. (Molex) facility located at 700 Kingbird Road, Lincoln, NE. The terms of the project are defined in a draft Final Project Agreement (FPA) which is being made available for public review and comment by this document. Also, EPA is making available for informational purposes a draft variance by the Nebraska Department of Environmental Quality necessary for implementation of the project. In addition, EPA is today promulgating a direct final site-specific rule, applicable only to the Molex facility, to facilitate implementation of the project. Also in today's **Federal Register**, EPA is publishing a proposed rule identical to this direct final rule. By this document, EPA solicits comment on the direct final rule, the draft variance, the draft FPA, and the project generally. Public notice is also being provided locally.

This direct final site-specific rule is intended to provide regulatory changes under the Resource Conservation and Recovery Act (RCRA) to implement

Molex's XL project, which will result in superior environmental performance and, at the same time, provide Molex with greater operational flexibility. The flexibility provided by Project XL will allow the facility to segregate waste streams which had previously been commingled into a single waste stream. By changing the process lines to generate separate waste streams (nickel, copper, tin/lead), the facility can optimize the precipitation of each metal more effectively before the effluent is sent to the POTW. The environmental benefit from the project will be a substantial reduction in the mass loading of metals entering the City of Lincoln's POTW. In addition, the resultant mono-metal sludges will be commodity-like materials suitable for recycling by smelters. A secondary environmental benefit will be increased recycling and reducing the amount of material that would otherwise be landfilled. The site-specific rule, applicable only to the Molex facility, would change certain RCRA requirements so the implementing agency, the Nebraska Department of Environmental Quality, may issue a temporary variance from classifying as solid waste nickel, copper, and tin/lead non-precious metals containing sludges generated by Molex.

DATES: This action will be effective January 2, 1998, unless adverse comments are received by December 3, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

Public Hearing. A public hearing will be held, if requested, to provide interested persons an opportunity for oral presentation of data, views, or arguments concerning this direct final rule to implement Molex's XL project. If anyone contacts the EPA requesting to speak at a public hearing by November 24, 1997, a public hearing will be held at 7:00 p.m. on December 15, 1997. EPA will determine no later than November 28, 1997 whether a public hearing will be held. Additional information is provided in the section entitled **ADDRESSES**.

Request to Speak at Hearing. Persons wishing to present oral testimony must contact Mr. David Doyle at the EPA by November 24, 1997. Additional information is provided in the section entitled **ADDRESSES**.

ADDRESSES: Comments. Written comments should be submitted in duplicate to: Mr. David Doyle, U.S. Environmental Protection Agency, Region VII, Air, RCRA & Toxics Division, 726 Minnesota Avenue, Kansas City, KS 66101, (913) 551-7667.

Docket. A docket containing supporting information used in developing this direct final rulemaking is available for public inspection and copying at U.S. EPA, Region VII, Air, RCRA & Toxics Division, 726 Minnesota Avenue, during normal business hours, and at EPA's Water docket (Docket name "XL-Molex"); 401 M Street, SW, Washington, DC 20460. For access to the Water docket materials, call (202) 260-3027 between 9:00 a.m. and 3:30 p.m. (Eastern time) for an appointment. A reasonable fee may be charged for copying. A docket is also available for public inspection at the Nebraska Department of Environmental Quality, Lincoln, NE.

Public Hearing. If a public hearing is held, it will be held at 7:00 p.m. on December 15, 1997 at the following location: Nebraska Department of Environmental Quality, Lincoln, NE. Persons interested in whether a hearing will be held should contact Mr. David Doyle, (913) 551-7667, after November 28, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. David Doyle, U.S. Environmental Protection Agency, Region VII, Air, RCRA & Toxics Division, 726 Minnesota Avenue, Kansas City, KS 66101, (913) 551-7667.

SUPPLEMENTARY INFORMATION:**Outline of This Document**

- I. Authority
- II. Background
 - A. Overview of Project XL
 - B. Overview of the Molex XL Project
 - 1. Introduction
 - 2. Molex XL Project Description
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 - 4. Stakeholder Involvement
- III. Resource Conservation and Recovery Act Requirements
- IV. Additional Information
 - A. Public Hearing
 - B. Executive Order 12866
 - C. Regulatory Flexibility
 - D. Paperwork Reduction Act
 - E. Unfunded Mandates Reform Act

I. Authority

This regulation is being promulgated under the authority of sections 1004, 2002, 3001-3007, and 3010 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act, as amended (42 U.S.C. 6903, 6912, 6921-6927, and 6930).

II. Background**A. Overview of Project XL**

This site-specific rule is designed to implement a project developed under Project XL, an important EPA initiative to allow regulated entities to achieve better environmental results at less cost.