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 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 September 23, 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 in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: July 12, 2002.

L. John Iani,

Regional Administrator, Region 10.

[FR Doc. 02–18869 Filed 7–24–02; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–7250–8]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste Final Exclusion

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA (also, ''the Agency'' or ''we'' in this preamble) is granting a petition submitted by Ormet Primary Aluminum Corporation (Ormet) to exclude (or ''delist'') vitrified spent potliner (VSP), generated and treated at the Ormet facility in Hannibal, Ohio from the lists of hazardous wastes. Spent potliners from primary aluminum reduction are listed as hazardous waste number K088 under the Resource Conservation and Recovery Act (RCRA).

Today's action conditionally excludes the petitioned waste from the list of hazardous wastes only if the waste is disposed of in a Subtitle D landfill which is permitted, licensed, or registered by a State to manage industrial solid waste.

EFFECTIVE DATE: This rule is effective on July 25, 2002.

ADDRESSES: The RCRA regulatory docket for this final rule, number R5-ORMT–01, is located at the U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604, and is available for viewing from 8 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. Call Todd Ramaly at (312) 353–9317 for appointments. The public may copy material from the regulatory docket at $0.15 per page.

FOR FURTHER INFORMATION CONTACT: For technical information concerning this document, contact Todd Ramaly at the address above or at (312) 353–9317.

SUPPLEMENTARY INFORMATION: The information in this section is organized as follows:

I. Background

A. What Is a Delisting Petition?

A delisting petition is a request from a generator to exclude waste from the list of hazardous wastes under RCRA regulations. In a delisting petition, the petitioner must show that waste generated at a particular facility does not meet any of the criteria for which EPA listed the waste as set forth in Title 40, Code of Federal Regulations (CFR) 261.11 and in the background document for the waste. A petitioner must demonstrate that the waste does not exhibit any of the hazardous waste characteristics (that is, ignitability, reactivity, corrosivity, and toxicity) and must present sufficient information for us to decide whether any factors other than those for which the waste was listed warrant retaining it as a hazardous waste.

A generator remains obligated under RCRA to confirm that its waste remains nonhazardous based on the hazardous waste characteristics even if EPA has ''delisted'' the wastes.

B. What Regulations Allow a Waste to Be Delisted?

Under 40 CFR 260.20 and 260.22, a generator may petition the EPA to remove its wastes from hazardous waste control by excluding it from the lists of hazardous wastes contained in §§ 261.31 and 261.32. Specifically, § 260.20 allows any person to petition the Administrator to modify or revoke any provision of parts 260 through 266, 268, and 273 of Title 40 of the Code of Federal Regulations. 40 CFR 260.22 provides a generator the opportunity to petition the Administrator to exclude a waste on a ''generator specific'' basis from the hazardous waste lists.

II. Ormet's Delisting Petition

A. What Waste Did Ormet Petition EPA To Delist?

On April, 8, 1994, Ormet submitted an up front petition to exclude vitrified spent potliner, K088, generated at its Hannibal Ohio plant from the list of hazardous wastes contained in 40 CFR 261.31. In December 1999, Ormet submitted a revised petition to exclude an annual volume of 8,500 cubic yards of K088 generated under full scale operation. K088 is defined as spent potliners from primary aluminum reduction.

B. What Information Must the Generator Supply?

A generator must provide sufficient information to allow the EPA to determine that the waste does not meet any of the criteria for which it was listed as a hazardous waste. In addition, where there is a reasonable basis to believe that factors other than those for which the waste was listed (including additional constituents) could cause the waste to be hazardous, the Administrator must determine that such factors do not warrant retaining the waste as hazardous.

C. What Information Did Ormet Submit To Support This Petition?

To support its petition, Ormet submitted descriptions and schematic diagrams of its manufacturing and vitrification processes and detailed chemical and physical analysis of the vitrified potliner.

III. EPA's Evaluation and Final Rule

A. What Decision Is EPA Finalizing and Why?

Today the EPA is finalizing an exclusion for 8500 cubic yards of vitrified spent potliner generated and treated annually at the Ormet facility in Hannibal, Ohio.

Ormet petitioned EPA to exclude, or delist, the vitrified spent potliner because Ormet believes that the petitioned waste does not meet the criteria for which it was listed it and that there are no additional constituents or factors which could cause the waste to be hazardous. Review of this petition included consideration of the original listing criteria, as well as the additional factors required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). See section 222 of HSWA, 42 United States Code (U.S.C.) 6921(f), and 40 CFR 260.22(d)(2)–(4).

On August 21, 2001 EPA proposed to exclude or delist Ormet's vitrified spent potliner from the list of hazardous wastes in 40 CFR 261.31 and accepted public comment on the proposed rule (66 FR 43823). EPA considered all comments received, and for reasons stated in both the proposal and this document, we believe that Ormet's waste should be excluded from hazardous waste control.

B. What Are the Terms of This Exclusion?

Ormet must dispose of the vitrified spent potliner in a Subtitle D landfill which is permitted, licensed, or registered by a state to manage industrial waste. Any amount exceeding 8,500 cubic yards, annually, is not considered delisted under this exclusion. This exclusion is effective only if all conditions contained in today's rule are satisfied.

C. When Is the Delisting Effective?

This rule is effective July 25, 2002. The Hazardous and Solid Waste Amendments of 1984 amended section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. This rule reduces rather than increases the existing requirements and, therefore, is effective immediately upon publication under the Administrative Procedure Act, pursuant to 5 U.S.C. 553(d).

D. How Does This Action Affect the States?

Because EPA is issuing today's exclusion under the federal RCRA delisting program, only states subject to federal RCRA delisting provisions would be affected. This exclusion may not be effective in states having a dual system that includes federal RCRA requirements and their own requirements, or in states which have received our authorization to make their own delisting decisions.

EPA allows states to impose their own non-RCRA regulatory requirements that are more stringent than EPA's, under section 3009 of RCRA. These more stringent requirements may include a provision that prohibits a federally issued exclusion from taking effect in the state. Because a dual system (that is, both federal (RCRA) and state (non-RCRA) programs) may regulate a petitioner's waste, we urge petitioners to contact the state regulatory authority to establish the status of their wastes under the state law.

EPA has also authorized some states to administer a delisting program in place of the federal program, that is, to make state delisting decisions. Therefore, this exclusion does not apply in those authorized states. If Ormet transports the petitioned waste to or manages the waste in any state with delisting authorization, Ormet must obtain a delisting from that state before it can manage the waste as nonhazardous in the state.

IV. Public Comments Received on the Proposed Exclusion and EPA's Responses

One comment was received from Ormet which pointed out that the proposed rule required sampling on a quarterly basis but required subsequent data submittals on a monthly basis. The discrepancy has been corrected. Verification sampling and data submittals are both required quarterly.

V. Regulatory Impact

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a rule of general applicability and therefore is not a ''regulatory action'' subject to review by the Office of Management and Budget. Because this action is a rule of particular applicability relating to a facility, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202, 204, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Because the rule will affect only one facility, it will not significantly or uniquely affect small governments, as specified in section 203 of UMRA, or impose substantial direct compliance costs on Indian tribal governments as specified in Executive Order 13175, 65 FR 67249, November 6, 2000. For the same reason, 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, or impose substantial direct compliance costs state and local governments as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This rule does not involve technical standards; thus, the requirements of section 12(c) 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, 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. 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.*).

VI. Congressional Review Act

The Congressional Review Act (5 U.S.C. 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 Congress and to the Comptroller General of the United States. EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability. Section 804 exempts from section 801 the following types of rules: rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non agency parties (5 U.S.C. 804(3)). This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will become effective on the date of publication in the **Federal Register**.

List of Subjects in 40 CFR Part 261

Environmental Protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Dated: July 9, 2002.

Phyllis A. Reed,

Acting Director, Waste, Pesticides and Toxins Division.

For the reasons set out in the preamble, 40 CFR part 261 is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

2. In Table 2 of Appendix IX to part 261 add the following waste stream in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22.

TABLE 2.—WASTES EXCLUDED FROM SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * * * *
Ormet Primary Aluminum Corporation.	Hannibal, OH	Vitrified spent potliner (VSP), K088, that is generated by Ormet Primary Aluminum Corporation in Hannibal (Ormet), Ohio at a maximum annual rate of 8,500 cubic yards per year and disposed of in a Subtitle D landfill, licensed, permitted, or registered by a state. The exclusion becomes effective as of July 25, 2002. 1. *Delisting Levels:* (A) The constituent concentrations measured in any of the extracts specified in paragraph (2) may not exceed the following levels (mg/L): Antimony—0.235; Arsenic—0.107; Barium—63.5; Beryllium—0.474; Cadmium—0.171; Chromium (total)—1.76; Lead—5; Mercury—0.17; Nickel—32.2; Selenium—0.661; Silver—4.38; Thallium—0.1; Tin—257; Vanadium—24.1; Zinc—320; Cyanide—4.11. (B) Land disposal restrictions (LDR) treatment standards for K088 must also be met before the VSP can be land disposed. Ormet must comply with any future LDR treatment standards promulgated under 40 CFR 268.40 for K088. 2. *Verification Testing:* (A) On a quarterly basis, Ormet must collect two samples of the waste and analyze them for the constituents listed in paragraph (1) using the methodologies specified in an EPA-approved sampling plan specifying (a) the TCLP method, and (b) the TCLP procedure with an extraction fluid of 0.1 Normal sodium hydroxide solution. The constituent concentrations measured in the extract must be less than the delisting levels established in paragraph (1). Ormet must also comply with LDR treatment standards in accordance with 40 CFR 268.40. (B) If the quarterly testing of the waste does not meet the delisting levels set forth in paragraph (1), Ormet must notify the Agency in writing in accordance with paragraph (5). The exclusion will be suspended and the waste managed as hazardous until Ormet has received written approval for the exclusion from the Agency. Ormet may provide sampling results that support the continuation of the delisting exclusion. 3. *Changes in Operating Conditions:* If Ormet significantly changes the manufacturing process, the treatment process, or the chemicals used, Ormet must notify the EPA of the changes in writing. Ormet must handle wastes generated after the process change as hazardous until Ormet has demonstrated that the wastes continue to meet the delisting levels set forth in paragraph (1) and that no new hazardous constituents listed in Appendix VIII of part 261 have been introduced and Ormet has received written approval from EPA. 4. *Data Submittals:* Ormet must submit the data obtained through quarterly verification testing or as required by other conditions of this rule to U.S. EPA Region 5, Waste Management Branch (DW–8J), 77 W. Jackson Blvd., Chicago, IL 60604 by February 1 of each calendar year for the prior calendar year. Ormet must compile, summarize, and maintain on site for a minimum of five years records of operating conditions and analytical data. Ormet must make these records available for inspection. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12). 5. *Reopener Language*—(a) If, anytime after disposal of the delisted waste, Ormet possesses or is otherwise made aware of any data (including but not limited to leachate data or groundwater monitoring data) relevant to the delisted waste indicating that any constituent identified in paragraph (1) is at a level in the leachate higher than the delisting level established in paragraph (1), or is at a level in the groundwater higher than the point of exposure groundwater levels referenced by the model, then Ormet must report such data, in writing, to the Regional Administrator within 10 days of first possessing or being made aware of that data. (b) Based on the information described in paragraph (5)(a) or any other information received from any source, the Regional Administrator will make a preliminary determination as to whether the reported information requires Agency action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (c) If the Regional Administrator determines that the information does require Agency action, the Regional Administrator will notify Ormet in writing of the actions the Regional Administrator believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing Ormet with an opportunity to present information as to why the proposed Agency action is not necessary or to suggest an alternative action. Ormet shall have 30 days from the date of the Regional Administrator's notice to present the information. (d) If after 30 days Ormet presents no further information, the Regional Administrator will issue a final written determination describing the Agency actions that are necessary to protect human health or the environment. Any required action described in the Regional Administrator's determination shall become effective immediately, unless the Regional Administrator provides otherwise.

TABLE 2.—WASTES EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
*	*	* * * * * * *

[FR Doc. 02–18711 Filed 7–24–02; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

RIN 0906–AA55

National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule.

SUMMARY: On July 13, 2001, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) proposing changes to the regulations governing the National Vaccine Injury Compensation Program (VICP). Specifically, the Secretary proposed revisions to the Vaccine Injury Table (the Table). The primary proposal made in the NPRM was that vaccines containing live, oral, rhesus-based rotavirus be added to the Table as a distinct category, with intussusception listed as a covered Table injury. This proposal was based upon the Secretary's determination that the condition of intussusception can reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus. The Secretary is now making this amendment to the Table by final rule. The Secretary is also making additional amendments to the Table and to the Table's Qualifications and Aids to Interpretation (Qualifications and Aids), described below under **SUPPLEMENTARY INFORMATION**, as proposed in the NPRM. The changes implemented here are authorized by section 2114(c) and (e) of the Public Health Service Act (the Act).

DATES: This regulation is effective on August 26, 2002. *Applicability dates:* As provided by section 13632(a)(3) of Public Law 103–66, the Omnibus Budget Reconciliation Act of 1993, the addition of vaccines containing live, oral, rhesus-based rotavirus took effect on October 22, 1998, the effective date of the excise tax for rotavirus vaccines, provided that they were administered on or before August 26, 2002. Under the same authority, the addition of pneumococcal conjugate vaccines took effect on December 18, 1999, the effective date of the excise tax for this categories of vaccines. See discussion under **SUPPLEMENTARY INFORMATION** in the NPRM underlying this final rule (66 FR 36735, July 13, 2001) for an explanation of these applicability dates.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Medical Director, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration (HRSA), Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–4198.

SUPPLEMENTARY INFORMATION:

Introductory and Procedural History

On July 13, 2001, the Secretary published in the **Federal Register** (66 FR 36735, July 13, 2001) an NPRM to revise and amend the Table and the Qualifications and Aids. The NPRM was issued pursuant to Section 2114(c) of the Act, which authorizes the Secretary to promulgate regulations to modify the Table, and Section 2114(e), which directed the Secretary to add to the Table, by rulemaking, coverage of additional vaccines which are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children.

The Department held a 6-month comment period, which ended on January 9, 2002, in connection with this NPRM. The Secretary did not receive any comments in response to the NPRM. A public hearing was held on December 6, 2001, as announced in the **Federal Register** (66 FR 58154, Nov. 20, 2001), but no individual or organization appeared to testify.

Because the Secretary has not received any comments, either written or oral, from any interested individual or organization on the proposals made in the NPRM, and because the Secretary continues to believe in the advisability of effectuating such proposals, this final rule implements the proposals made in the NPRM. One technical amendment to 42 CFR 100.3(c)(4), which was inadvertently omitted from the NPRM, is being implemented in this final rule. In addition, we are modifying the authority citation for 42 CFR part 100. The rationales for all other revisions and additions made in this final rule were explained fully in the Preamble to the NPRM. For the reasons set forth in the NPRM, the Secretary makes several amendments affecting the operation of the VICP in this rule.

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety distributive, and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget. Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Secretary has determined that no resources are required to implement the requirements in this rule. Compensation will be made in the same manner. The final rule only lessens the burden of proof for certain potential petitioners. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.