ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–7008–1]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: The EPA is proposing to grant a petition submitted by Texas Arai Manufacturing Facility (Texas Arai) to exclude (or delist) certain solid wastes generated by its Houston, Texas, facility from the lists of hazardous wastes.

The Agency bases its proposed decision to grant the petition on an evaluation of waste-specific information provided by the petitioner. This proposed decision, if finalized, would conditionally exclude the petitioned waste from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

The EPA is proposing to use the Delisting Risk Assessment Software (DRAS) in the evaluation of the delisting petition. Based on waste specific information provided by the petitioner, EPA is proposing to use the DRAS to evaluate the impact of the petitioned waste on human health and the environment.

If finalized, we would conclude that Texas Arai's petitioned waste is nonhazardous with respect to the original listing criteria and that the wastewater treatment process Texas Arai uses will substantially reduce the likelihood of migration of hazardous constituents from this waste. We would also conclude that its process minimizes short-term and long-term threats from the petitioned waste to human health and the environment.

DATES: We will accept comments until August 27, 2001. We will stamp comments received after the close of the comment period as ''late''. These late'' comments may not be considered in formulating a final decision. Your requests for a hearing must reach EPA by July 30, 2001. The request must contain the information prescribed in § 260.20(d).

ADDRESSES: Please send three copies of your comments. You should send two copies to William Gallagher, Delisting Section, Multimedia Planning and Permitting Division (6PD–O), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas, 75202. A third copy should be sent to the Texas Natural Resource Conservation Commission (TNRCC), P.O. Box 13087, Austin, Texas, 78711–3087. Identify your comments at the top with this regulatory docket number: ''F–00–TXDEL–Texas Arai.''

You should address requests for a hearing to the Director, Carl Edlund, Multimedia Planning and Permitting Division (6PD), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202.

FOR FURTHER INFORMATION CONTACT: Deanna R. Lacy at (214) 665–6461.

SUPPLEMENTARY INFORMATION:

The information in this section is organized as follows:

I. Overview Information

A. What Action Is EPA Proposing?

The EPA is proposing:

(1) To grant Texas Arai's petition to have its F006 wastewater treatment sludge excluded, or delisted, from the definition of a hazardous waste, subject to certain continued verification and monitoring conditions; and

(2) To use a fate and transport model to evaluate the potential impact of the petitioned waste on human health and the environment. The Agency would use this model to predict the concentration of hazardous constituents released from the petitioned waste, once it is disposed.

B. Why Is EPA Proposing To Approve This Delisting?

Texas Arai's petition requests a delisting for listed hazardous wastes. Texas Arai does not believe that the petitioned waste meets the criteria for which EPA listed it. Texas Arai also believes no additional constituents or factors could cause the waste to be hazardous. The EPA's review of this petition included consideration of the original listing criteria, and the additional factors required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). See section 3001(f) of RCRA, 42 U.S.C. 6921(f), and 40 CFR 260.22(d)(1)–(4). In making the initial delisting determination, EPA evaluated the petitioned waste against the listing criteria and factors cited in §§ 261.11(a)(2) and (a)(3). Based on this review, the EPA agrees with the petitioner that the waste is nonhazardous with respect to the original listing criteria. (If the EPA had found, based on this review, that the waste remained hazardous based on the factors for which the waste was originally listed, EPA would have proposed to deny the petition.) The EPA evaluated the waste with respect to other factors or criteria to assess whether there is a reasonable basis to believe that such additional factors could cause the waste to be hazardous. The EPA considered whether the waste is acutely toxic, the concentration of the constituents in the waste, their tendency to migrate and to bioaccumulate, their persistence in the environment once released from the waste, plausible and specific types of management of the petitioned waste, the quantities of waste generated, and waste variability. The EPA believes that the petitioned waste does not meet these criteria. EPA's proposed decision to delist waste from

Texas Arai's facility is based on the information submitted in support of this proposal, i.e., descriptions of the wastewater treatment system, and analytical data from the Houston facility.

C. How Will Texas Arai Manage the Waste if it Is Delisted?

Texas Arai currently disposes of the wastewater treatment sludge by transporting it to a disposal facility, Phillips Services (formerly Eltex Chemical) in Houston. Then, according to Phillips Services, it is transported to Texas Ecologists located in Robstown, Texas, for stabilization and final disposal. If delisted, Texas Arai plans to manage the wastewater treatment sludge as a Class I nonhazardous industrial solid waste, and proposes to dispose of the sludge at an approved and permitted industrial waste landfill to be determined pending successful completion of the petition.

D. When Would EPA Finalize the Proposed Delisting?

RCRA section 3001(f) specifically requires EPA to provide proposal and an opportunity for comment before granting or denying a final exclusion. Thus, EPA will not grant the exclusion until it addresses all timely public comments (including those at public hearings, if any) on this proposed rule.

RCRA section 3010(b)(1) at 42 U.S.C.A. 6930(b)(1), allows rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here, because this rule, if finalized, would reduce the existing requirements for persons generating hazardous wastes.

The EPA believes that this exclusion should be effective immediately upon final publication because a six-month deadline is not necessary to achieve the purpose of § 3010(b), and a later effective date would impose unnecessary hardship and expense on this petitioner. These reasons also provide good cause for making this rule effective immediately, upon final publication, under the Administrative Procedure Act, 5 U.S.C. 553(d).

E. How Would This Action Affect the States?

Because EPA is issuing this exclusion under the Federal RCRA delisting program, only States subject to Federal RCRA delisting provisions would be affected. This would exclude two categories of States: States having a dual system that includes Federal RCRA requirements and their own requirements, and States which have received authorization from EPA to make their own delisting decisions.

Here are the details: We allow states to impose their own non-RCRA regulatory requirements that are more stringent than EPA's under § 3009 of RCRA, 42 U.S.C.A. 6929. 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.

The EPA has also authorized some States (for example, Louisiana, Georgia, Illinois) to administer a RCRA 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 unless that State makes the rule part of its authorized program. If Texas Arai transports the petitioned waste to or manages the waste in any State with delisting authorization, Texas Arai must obtain delisting authorization from that State before they can manage the waste as nonhazardous in that State.

II. Background

A. What Is the History of the Delisting Program?

The EPA published an amended list of hazardous wastes from nonspecific and specific sources on January 16, 1981, as part of its final and interim final regulations implementing section 3001 of RCRA. The EPA has amended this list several times and published it in §§ 261.31 and 261.32.

We list these wastes as hazardous because: (1) They typically and frequently exhibit one or more of the characteristics of hazardous wastes identified in Subpart C of Part 261 (that is, ignitability, corrosivity, reactivity, and toxicity) or (2) they meet the criteria for listing contained in §§ 261.11(a)(2) or (a)(3).

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste described in these regulations generally is hazardous, a specific waste from an individual facility meeting the listing description may not be hazardous.

For this reason, §§ 260.20 and 260.22 provide an exclusion procedure, called delisting, which allows persons to prove that EPA should not regulate a specific waste from a particular generating facility as a hazardous waste.

B. What Is a Delisting Petition, and What Does it Require of a Petitioner?

A delisting petition is a request from a facility to EPA or an authorized State to exclude wastes from the list of hazardous wastes. The facility petitions the Agency because it does not consider the wastes hazardous under RCRA regulations.

In a delisting petition, the petitioner must show that wastes generated at a particular facility do not meet any of the criteria for which a waste was listed wastes. The criteria for which EPA lists a waste are in Part 261 further explains and in the background documents for the listed waste.

In addition, under § 260.22, a petitioner must prove that the waste does not exhibit any of the hazardous waste characteristics (that is, ignitability, reactivity, corrosivity, and toxicity) and present sufficient information for EPA to decide whether factors other than those for which the waste was listed warrant retaining it as a hazardous waste. (See Part 261 and the background documents for the listed wastes.)

Generators remain obligated under RCRA to confirm whether their waste remains nonhazardous based on the hazardous waste characteristics even if EPA has ''delisted'' the waste.

C. What Factors Must EPA Consider in Deciding Whether To Grant a Delisting Petition?

Besides considering the criteria in § 260.22(a) and § 3001(f) of RCRA, 42 U.S.C. 6921(f), and in the background documents for the listed wastes, EPA must consider any factors (including additional constituents) other than those for which we listed the waste if a reasonable basis exists that these additional factors could cause the waste to be hazardous.

The EPA must also consider as hazardous waste mixtures containing listed hazardous wastes and wastes derived from treating, storing, or disposing of listed hazardous waste. See §§ 261.3(a)(2)(iii and iv) and (c)(2)(i), called the ''mixture'' and ''derived-from'' rules, respectively. These wastes are also eligible for exclusion and remain hazardous wastes until excluded.

The ''mixture'' and ''derived-from'' rules are now final, after having been vacated, remanded, and reinstated. On December 6, 1991, the U.S. Court of Appeals for the District of Columbia vacated the ''mixture/derived from'' rules and remanded them to EPA on procedural grounds. See *Shell Oil Co.* v. *EPA.*, 950 F.2d 741 (DC Cir. 1991). On

March 3, 1992, EPA reinstated the mixture and derived-from rules, and solicited comments on other ways to regulate waste mixtures and residues. See (57 *FR* 7628). These rules became final on October 30, 1992. See (57 *FR* 49278). Consult these references for more information about mixtures and derived from wastes.

III. EPA's Evaluation of the Waste Information and Data

A. What Waste Did Texas Arai Petition EPA To Delist?

On April 13, 2000, Texas Arai petitioned the EPA to exclude from the lists of hazardous waste contained in §§ 261.31 and 261.32 a F006 wastewater treatment sludge generated from the treatment of process wastewater associated with metal plating and finishing operations. Specifically, in its petition, Texas Arai located in Houston, Texas, requested that EPA grant an exclusion for 186 cubic yards per year of wastewater treatment sludge resulting from its hazardous waste treatment process.

B. Who Is Texas Arai and What Process Do They Use To Generate the Petitioned Waste?

Texas Arai is a manufacturing facility in Houston, TX which has been in operation since 1981 and began its generation of the petitioned waste in 1997. Texas Arai produces carbon steel couplings for the petroleum and petrochemical industry.

The facility machines tubular carbon steel into threaded couplings which are then finished by chromium steel plating, followed by paint marking and packaging. The couplings are machined from raw carbon steel and alloy metals and are plated to American Petroleum Institute (API) specifications. Metal finishing and plating operations generate wastewater which is treated in an on-site wastewater treatment system prior to discharge. Hazardous wastes generated during facility operations include: wastewater treatment sludge, zinc phosphate solution, alkaline cleaning solution, spent solvents, and spent paint wastes. The petitioned waste has been disposed of as a hazardous waste at Texas Ecologists in Robstown, Texas. The waste code of the constituents of concern is EPA Hazardous Waste No. F006. The constituents of concern for F006 are cadmium, hexavalent chromium, nickel, and cyanide (complexed).

C. How Did Texas Arai Sample and Analyze the Waste Data in This Petition?

Four grab samples were collected each week over a period of five weeks. The grab sample locations were selected using a random sampling strategy. Each of the four grab samples were combined into a single composite sample. Samples were collected from two trays underlying the filter press. Sampling was conducted by Dames & Moore consulting firm.

To support its petition, Texas Arai submitted:

(1) Descriptions of its wastewater treatment system associated with petitioned wastes;

(2) Results of the total constituent list for 40 CFR Part 264 Appendix IX volatiles, semivolatiles, and metals except pesticides, herbicides, and PCBs;

(3) Results of the constituent list for Appendix IX on Toxicity Characteristic Leaching Procedure (TCLP) extract for volatiles, semivolatiles, and metals;

(4) Results for total sulfide,

(5) results for total cyanide;

(6) Results for pH;

(7) Results of the metals; amd

(9) Results from oil and grease.

D. What Were the Results of Texas Arai's Analyses?

The EPA believes that the descriptions of the Texas Arai hazardous waste process and analytical characterization provide a reasonable basis to grant Texas Arai's petition for an exclusion of the wastewater treatment sludge. The EPA believes the data submitted in support of the petition show Texas Arai's process renders the wastewater treatment sludge nonhazardous. The EPA has reviewed the sampling procedures used by Texas Arai and has determined they satisfy EPA criteria for collecting representative samples of the variations in constituent concentrations in the wastewater treatment sludge. The data submitted in support of the petition show that constituents in Texas Arai's waste are presently below health-based levels used in the delisting decision-making. The EPA believes that Texas Arai has successfully demonstrated that the wastewater treatment sludge is nonhazardous.

E. How Did EPA Evaluate the Risk of Delisting the Waste?

For this delisting determination, EPA used such information gathered to identify plausible exposure routes (i.e., ground water, surface water, air) for hazardous constituents present in the petitioned waste. The EPA determined that disposal in a Subtitle D landfill is the most reasonable, worst-case disposal scenario for Texas Arai's petitioned waste. The EPA applied the Delisting Risk Assessment Software (DRAS) described in 65 FR 58015 (September 27, 2000) and 65 FR 75637 (December 4, 2000) to predict the maximum allowable concentrations of hazardous constituents that may release from the petitioned waste after disposal and determined the potential impact of the disposal of Texas Arai's petitioned waste on human health and the environment. In assessing potential risks to ground water, specifically, EPA used the maximum estimated waste volumes and the maximum reported extract concentrations as inputs to the DRAS program to estimate the constituent concentrations in the ground water at a hypothetical receptor well down gradient from the disposal site. Using the risk level (carcinogenic risk of 10–5 and non-cancer hazard index of 0.1), the DRAS program can back-calculate the acceptable receptor well concentrations (referred to as compliance-point concentrations) using standard risk assessment algorithms and Agency health-based numbers. Using the maximum compliance-point concentrations and the EPACMTP fate and transport modeling factors, the DRAS further back-calculates the maximum permissible waste constituent concentrations not expected to exceed the compliance-point concentrations in ground water.

The EPA believes that the EPACMTP fate and transport model represents a reasonable worst-case scenario for possible ground water contamination resulting from disposal of the petitioned waste in a landfill, and that a reasonable worst-case scenario is appropriate when evaluating whether a waste should be relieved of the protective management constraints of RCRA Subtitle C. The use of some reasonable worst-case scenario results in conservative values for the compliance-point concentrations and ensures that the waste, once removed from hazardous waste regulation, will not pose a significant threat to human health or the environment.

Similarly, the DRAS used the maximum estimated waste volumes and the maximum reported total concentrations to predict possible risks associated with releases of waste constituents through surface pathways (*e.g.*, volatilization or wind-blown particulate from the landfill). In the ground water analyses, the DRAS uses the established acceptable risk level, the health-based data and standard risk assessment and exposure algorithms to predict maximum compliance-point

concentrations of waste constituents at a hypothetical point of exposure. Using fate and transport equations, the DRAS uses the maximum compliance-point concentrations and back-calculates the maximum allowable waste constituent concentrations (or ''delisting levels''). In most cases, because a delisted waste is no longer subject to hazardous waste control, EPA is generally unable to predict, and does not presently control, how a petitioner will manage a waste after delisting. Therefore, EPA currently believes that it is inappropriate to consider extensive site-specific factors when applying the fate and transport model.

The EPA also considers the applicability of ground water monitoring data during the evaluation of delisting petitions. In this case, Texas Arai does not dispose of waste onsite, therefore, no groundwater data is available.

From the evaluation of Texas Arai's delisting petition, EPA developed a list of constituents for the verification testing conditions. Proposed maximum allowable leachable concentrations for these constituents were derived by back-calculating from the delisting health-based levels through the proposed fate and transport model for a landfill management scenario. These concentrations (i.e., ''delisting levels'') are part of the proposed verification testing conditions of the exclusion.

The EPA believes that the descriptions of the Texas Arai, Inc., hazardous waste process and analytical characterization, in conjunction with the proposed testing requirements (as discussed later in this proposed exclusion) provide a reasonable basis to conclude that the likelihood of migration of hazardous constituents from the petitioned waste will be substantially reduced so that short-term and long-term threats to human health and the environment are minimized. Thus, EPA should grant Texas Arai's petition for a standard conditional exclusion of the wastewater treatment sludge.

The EPA Region 6 Delisting Program guidance document states that the appropriate fate and effect model will be used to determine the effect the petitioned waste could have on human health if it is not managed as a hazardous waste. Specifically, the model considers the maximum estimated waste volume and the maximum reported leachate concentrations as inputs to estimate the constituent concentrations in the ground water at a hypothetical receptor well downgradient from the disposal site. The calculated receptor well concentrations (referred to as compliance-point concentrations) are then compared directly to the health-based levels used in delisting decision-making for hazardous constituents of concern. EPA Region 6 has selected the DRAS as the appropriate model for the delisting program. This subsection presents an evaluation of the potential for ground water contamination for the petitioned waste using the DRAS.

The EPA considered the appropriateness of alternative waste management scenarios for Texas Arai's wastewater treatment sludge. The EPA decided, based on the information provided in the petition, that disposal of the wastewater treatment sludge in a municipal solid waste landfill is the most reasonable, worst-case scenario for the wastewater treatment sludge. Under a landfill disposal scenario, the major exposure route of concern for any hazardous constituents would be ingestion of contaminated ground water. The EPA, therefore, evaluated Texas Arai's petitioned waste using DRAS which predicts the potential for ground water contamination from waste placed in a landfill.

For the evaluation of Texas Arai's petitioned waste, EPA used the DRAS to evaluate the mobility of the hazardous constituents detected in the extract of samples of Texas Arai's wastewater treatment sludge. Total analysis was also utilized for the wastewater treatment sludge. The maximum annual waste volume for Texas Arai is 186 cubic yards per year. The Dilution Attenuation Factors are currently calculated assuming an ongoing process generates waste for 20 years.

Analytical data for the wastewater treatment sludge samples were used in the model. The data summaries for detected constituents are presented in Table I. The data in this table shows that the Maximum Total concentration in the waste is low and if leached, the waste would not pose a significant risk to the environment.

The EPA's evaluation of the wastewater treatment sludge is based on the maximum reported Total and TCLP concentrations (See Table II). Based on the DRAS, the petitioned waste should be delisted because no constituents of concern exceed the delisting concentrations.

TABLE I.—MAXIMUM TOTAL AND TCLP CONSTITUENT CONCENTRATIONS WASTEWATER TREATMENT SLUDGE [1]

Constituent	Total constituent analyses (mg/kg) (SW–846, Method 8240, 8260, 8030, 8020, 8010, 8015, 8270, 8080, 8150, 6010, 7470, 7870, 9030, 9010, 9040)	TCLP leachate concentration (mg/1) (SW–846, method 1311)
Aluminum	643	ND(0.1)
Arsenic	3.55	ND(0.1)
Barium	37.4	ND(0.1)
Chromium	70.7	(0.1)
Chromium (VI)	0.1	N/A
Cobalt	3.63	0.021
Copper	33.6	ND(0.02)
Manganese	862	7
Nickel	2560	14.9
Tin	10800	0.92
Zinc	19300	9.5
Ethylbenzene	0.022	ND(0.005)
Xylenes	0.073	ND(0.005)
Carbon Disulfide	0.28	ND(0.005)
Methylene Chloride	0.017	ND(0.05)
Acetonitrile	0.21	0.21
Allyl Chloride	0.018	0.018
bis(2-ethylhexyl) phthlate	4.4	ND(0.005)
Chloride	549	N/A

TABLE I.—MAXIMUM TOTAL AND TCLP CONSTITUENT CONCENTRATIONS WASTEWATER TREATMENT SLUDGE [1]—Continued

Constituent	Total constituent analyses (mg/kg) (SW–846, Method 8240, 8260, 8030, 8020, 8010, 8015, 8270, 8080, 8150, 6010, 7470, 7870, 9030, 9010, 9040)	TCLP leachate concentration (mg/1) (SW–846, method 1311)
Sulfides	24200	N/A
pH	8.94	N/A

[1] These levels represent the highest concentration of each constituent found in any one sample. These levels do not necessarily represent the specific levels found in one sample.
ND Denotes that the constituent was not detected at the method detection limit specified in the table.
N/A Not Applicable.

TABLE II.—MAXIMUM ALLOWABLE CONCENTRATIONS OF CONSTITUENTS IN LEACHATE

Constituent	Maximum allowable leachate concentration (mg/L)
Allyl Chloride	0.187
Acetonitrile	21.3
Arsenic	0.163
Barium	100
Bis (2-ethylhexyl) phthalate	4.88
Carbon Disulfide	2.94
Chromium	5.0
Cobalt	39.3
Copper	130
Ethylbenzene	3.33
Manganese	91.7
Methylene Chloride	3.95
Nickel	49.3
Tin	393.0
Xylenes	104.0
Zinc	489.0

F. What did EPA Conclude About Texas Arai's Analysis?

The EPA concluded, after reviewing Texas Arai's processes, that no other hazardous constituents of concern, other than those for which tested, are likely to be present or formed as reaction products or by products in Texas Arai's waste. In addition, on the basis of explanations and analytical data provided by Texas Arai pursuant to § 260.22, the EPA concludes that the petitioned waste does not exhibit any of the characteristics of ignitability, corrosivity, or reactivity. See, §§ 261.21, 261.22, and 261.23, respectively.

G. What Other Factors Did EPA Consider in Its Evaluation?

During the evaluation of Texas Arai's petition, EPA also considered the potential impact of the petitioned waste via non-ground water routes (i.e., air emission and surface runoff). With regard to airborne dispersion in particular, EPA believes that exposure to airborne contaminants from Texas Arai's petitioned waste is unlikely. Therefore, no appreciable air releases are likely from Texas Arai's waste under any likely disposal conditions. The EPA evaluated the potential hazards resulting from the unlikely scenario of airborne exposure to hazardous constituents released from Texas Arai's waste in an open landfill. The results of this worst-case analysis indicated that there is no substantial present or potential hazard to human health and the environment from airborne exposure to constituents from Texas Arai's Wastewater treatment sludge. A description of EPA's assessment of the potential impact of Texas Arai's waste, regarding airborne dispersion of waste contaminants, is presented in the RCRA public docket for the proposed rule F–00–TXDEL–TXARAI.

The EPA also considered the potential impact of the petitioned waste via a surface water route. The EPA believes that containment structures at municipal solid waste landfills can effectively control surface water runoff, as the Subtitle D regulations (See 56 *FR* 50978, October 9, 1991) prohibit pollutant discharges into surface waters. Furthermore, the concentrations of any hazardous constituents dissolved in the runoff will tend to be lower than the levels in the TCLP leachate analyses reported in this proposed rule due to the aggressive acidic medium used for extraction in the TCLP. The EPA believes that, in general, leachate derived from the waste is unlikely to directly enter a surface water body without first traveling through the saturated subsurface where dilution and attenuation of hazardous constituents will also occur. Leachable concentrations provide a direct measure of solubility of a toxic constituent in water and are indicative of the fraction of the constituent that may be mobilized in surface water as well as ground water.

Based on the reasons discussed above, EPA believes that the contamination of surface water through runoff from the waste disposal area is very unlikely. Nevertheless, EPA evaluated the potential impacts on surface water if Texas Arai's waste were released from a municipal solid waste landfill through runoff and erosion. See the RCRA public docket for the proposed rule for further information on the potential surface water impacts from runoff and erosion. The estimated levels of the hazardous constituents of concern in surface water would be well below health-based levels for human health, as well as below EPA Chronic Water Quality Criteria for aquatic organisms (USEPA, OWRS, 1987). The EPA, therefore, concluded that Texas Arai's wastewater treatment sludge is not a present or potential substantial hazard to human health and the environment via the surface water exposure pathway.

H. What Is EPA's Final Evaluation of This Delisting Petition?

The descriptions of Texas Arai's hazardous waste process and analytical characterization, with the proposed verification testing requirements (as discussed later in this proposed exclusion) provide a reasonable basis for EPA to grant the exclusion. The data submitted in support of the petition show that constituents in the waste are below the maximum allowable leachable concentrations (see Table II). We believe Texas Arai has an effective treatment process that has rendered the waste as nonhazardous.

Thus, EPA believes we should grant Texas Arai an exclusion for the wastewater treatment sludge. The EPA believes the data submitted in support of the petition show Texas Arai's process renders the wastewater treatment sludge nonhazardous.

We have reviewed the sampling procedures used by Texas Arai and have determined they satisfy EPA criteria for collecting representative samples of variable constituent concentrations in the wastewater treatment sludge. The data submitted in support of the petition show that constituents in Texas Arai's waste are presently below the compliance point concentrations used in the delisting decision-making and do not pose a substantial hazard to the environment. The EPA believes that Texas Arai has successfully demonstrated that the wastewater treatment sludge is nonhazardous.

The EPA therefore, proposes to grant a standard conditional exclusion to the Texas Arai, in Houston, Texas, for the wastewater treatment sludge described in its petition. The EPA's decision to conditionally exclude this waste is based on descriptions of the treatment activities associated with the petitioned waste and characterization of the wastewater treatment sludge.

If we finalize the proposed rule, the Agency will no longer regulate the petitioned waste under parts 262 through 268 and the permitting standards of part 270.

IV. Next Steps

A. With What Conditions Must the Petitioner Comply?

The petitioner, Texas Arai, must comply with the requirements in 40 CFR part 261, Appendix IX, Table 1. The text below gives the rationale and details of those requirements.

(1) Delisting Levels

This paragraph provides the levels of constituents Texas Arai must test the leachate from the wastewater treatment sludge, below which these wastes would be considered nonhazardous.

The EPA selected the set of inorganic and organic constituents specified in Paragraph (1) because of information in the petition. We compiled the list from the composition of the waste, descriptions of Texas Arai's treatment process, previous test data provided for the waste, and the respective health-based levels used in delisting decision-making.

These delisting levels correspond to the allowable levels measured in the TCLP extract of the waste.

(2) Waste Holding and Handling

The purpose of this paragraph is to ensure that any wastewater treatment sludge which might contain hazardous levels of inorganic and organic constituents are managed and disposed of in accordance with Subtitle C of RCRA. If EPA determines that the data collected under this condition do not support the data provided in the petition, the exclusion will not cover the petitioned waste.

(3) Verification Testing Requirements

Although the wastewater treatment sludge is considered delisted upon promulgation of this rule, EPA believes that conditional testing requirements are still warranted to ensure continued effectiveness of the treatment process. During the verification period, which is described in paragraph (3)(A)(i), Texas Arai must collect four samples quarterly for a period of one year. After successful completion of the initial verification period, which is approximately 12 months from the date of promulgation of the final rule, Texas Arai may begin annual sampling of the wastewater treatment sludge.

(A) *Testing.* The EPA believes that the concentrations of the constituents of concern in the wastewater treatment sludge may vary over time. Therefore, EPA believes that quarterly sampling of this waste is adequate for Texas Arai to collect sufficient data to verify that the data provided for the wastewater treatment sludge is representative. Texas Arai may dispose of the sludge as a nonhazardous waste during the initial verification period if the waste meets the exclusion levels of Paragraph (1). Texas Arai would begin annual sampling on the first anniversary date of the final exclusion if the quarterly sampling is completed.

(4) Changes in Operating Conditions

Paragraph (4) would allow Texas Arai the flexibility of modifying its processes (for example, changes in equipment or changes in operating conditions) to improve its treatment process. However, Texas Arai must prove the effectiveness of the modified process and request approval from the EPA. Texas Arai must manage wastes generated during the new process demonstration as hazardous waste until it has obtained written approval and Paragraph (3) is satisfied.

(5) Data Submittals

To provide appropriate documentation that Texas Arai's facility is properly treating the waste, Texas Arai must compile, summarize, and keep delisting records on-site for a minimum of five years. It should keep all analytical data obtained through Paragraph (3) including quality control information for five years. Paragraph (5) requires that Texas Arai furnish these data upon request for inspection by any employee or representative of EPA or the State of Texas.

If the proposed exclusion is made final, it will apply only to 186 cubic yards of wastewater treatment sludge, generated annually at the Texas Arai facility after successful verification testing.

We would require Texas Arai to file a new delisting petition under any of the following circumstances:

(a) If it uses any new manufacturing or production process(es), or significantly change from the current process(es) described in its petition; or

(b) If it makes any changes that could affect the composition or type of waste generated.

Texas Arai must manage annual waste volumes greater than 186 cubic yards of wastewater treatment sludge as hazardous unless or until we grant a new exclusion.

If this exclusion becomes final, Texas Arai's management of the wastes covered by this petition would be relieved from Subtitle C jurisdiction. Texas Arai must ensure that it delivers the waste to an off-site storage, treatment, or disposal facility that has a State permit, license, or is registered to manage municipal or industrial solid waste.

(6) Reopener Language

The purpose of Paragraph 6 is to require Texas Arai to disclose new or different information related to a condition at the facility or disposal of the waste if it is pertinent to the delisting. Texas Arai must also use this procedure, if the waste sample in the annual testing fails to meet the levels found in Paragraph 1. This provision will allow EPA to reevaluate the exclusion if a source provides new or additional information to the Agency. The EPA will evaluate the information on which we based the decision to see if it is still correct, or if circumstances have changed so that the information is no longer correct or would cause EPA to deny the petition if presented. This provision expressly requires Texas Arai to report differing site conditions or assumptions used in the petition in addition to failure to meet the annual testing conditions within 10 days of discovery. If EPA discovers such information itself or from a third party, it can act on it as appropriate. The language being proposed is similar to those provisions found in RCRA regulations governing no-migration petitions at § 268.6.

The EPA believes that we have the authority under RCRA and the Administrative Procedures Act, 5 U.S.C. 551 (1978) *et seq.*, to reopen a delisting decision. We may reopen a delisting decision when we receive new information that calls into question the assumptions underlying the delisting.

The Agency believes a clear statement of its authority in delistings is merited in light of Agency experience. *See* Reynolds Metals Company at 62 FR 37694 (July 14, 1997) and 62 FR 63458 (December 1, 1997) where the delisted waste leached at greater concentrations in the environment than the concentrations predicted when conducting the TCLP, thus leading the Agency to repeal the delisting. If an immediate threat to human health and the environment presents itself, EPA will continue to address these situations

case by case. Where necessary, EPA will make a good cause finding to justify emergency rulemaking. *See* APA § 553 (b).

(7) Notification Requirements

In order to adequately track wastes that have been delisted, EPA is requiring that Texas Arai provide a one-time notification to any State regulatory agency through which or to which the delisted waste is being carried. Texas Arai must provide this notification within 60 days of commencing this activity.

B. What Happens if Texas Arai Violates the Terms and Conditions?

If Texas Arai violates the terms and conditions established in the exclusion, the Agency will start procedures to withdraw the exclusion. Where there is an immediate threat to human health and the environment, the Agency will continue to evaluate the need for enforcement activities on a case-by-case basis. The Agency expects Texas Arai to conduct the appropriate waste analysis and comply with the criteria explained above in Paragraphs 1, 2, 3, 4, 5 and 6 of the exclusion.

VI. Public Comments

A. How Can I as an Interested Party Submit Comments?

The EPA is requesting public comments on this proposed decision. Please send three copies of your comments. Send two copies to William Gallagher, Delisting Section, Multimedia Planning and Permitting Division (6PD–O), Environmental Protection Agency (EPA), Region 6, 1445 Ross Avenue, Dallas, Texas 75202. Send a third copy to the Texas Natural Resource Conservation Commission, 12100 Park 35 Circle, Austin, Texas 78753. Identify your comments at the top with this regulatory docket number: ''F–00–TXDEL–Texas Arai.''

You should submit requests for a hearing to Carl Edlund, Director, Multimedia Planning and Permitting Division (6PD), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202.

B. How May I Review the Docket or Obtain Copies of the Proposed Exclusion?

You may review the RCRA regulatory docket for this proposed rule at the Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202. It is available for viewing in the EPA Freedom of Information Act Review Room from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. Call (214) 665–6444 for appointments. The public may copy material from any regulatory docket at no cost for the first 100 pages, and at fifteen cents per page for additional copies.

VI. Regulatory Impact

Under Executive Order 12866, EPA must conduct an ''assessment of the potential costs and benefits'' for all ''significant'' regulatory actions.

The proposal to grant an exclusion is not significant, since its effect, if promulgated, would be to reduce the overall costs and economic impact of EPA's hazardous waste management regulations. This reduction would be achieved by excluding waste generated at a specific facility from EPA's lists of hazardous wastes, thus enabling a facility to manage its waste as nonhazardous.

Because there is no additional impact from the proposed rule, this proposal would not be a significant regulation, and no cost/benefit assessment is required. The Office of Management and Budget (OMB) has also exempted this rule from the requirement for OMB review under Section (6) of Executive Order 12866.

VII. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, whenever an agency is required to publish a general of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (that is, small businesses, small organizations, and small governmental jurisdictions). No regulatory flexibility analysis is required, however, if the Administrator or delegated representative certifies that the rule will not have any impact on small entities.

This rule, if promulgated, will not have an adverse economic impact on small entities since its effect would be to reduce the overall costs of EPA's hazardous waste regulations and would be limited to one facility. Accordingly, I hereby certify that this proposed regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

VIII. Paperwork Reduction Act

Information collection and record-keeping requirements associated with this proposed rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Public Law 96–511, 44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2050–0053.

IX. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, which was signed into law on March 22, 1995, EPA generally must prepare a written statement for rules with Federal mandates that may result in estimated costs to State, local, and tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year.

When such a statement is required for EPA rules, under section 205 of the UMRA, EPA must identify and consider alternatives, including the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The EPA must select that alternative, unless the Administrator explains in the final rule why it was not selected or it is inconsistent with law.

Before EPA establishes regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must develop under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, giving them meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising them on compliance with the regulatory requirements.

The UMRA generally defines a Federal mandate for regulatory purposes as one that imposes an enforceable duty upon state, local, or tribal governments or the private sector.

The EPA finds that the delisting decision is deregulatory in nature and does not impose any enforceable duty on any State, local, or tribal governments or the private sector. In addition, the proposed delisting decision does not establish any regulatory requirements for small governments and so does not require a small government agency plan under UMRA section 203.

X. Executive Order 13045

The Executive Order 13045 is entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This order applies to any rule that EPA determines (1) is economically significant as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets

both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This proposed rule is not subject to Executive Order 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866.

XI. Executive Order 13084

Because this action does not involve any requirements that affect Indian Tribes, the requirements of section 3(b) of Executive Order 13084 do not apply.

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments.

If the mandate is unfunded, EPA must provide to the Office Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to meaningful and timely input'' in the development of regulatory policies on matters that significantly or uniquely affect their communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

XII. National Technology Transfer and Advancement Act

Under Section 12(d) of the National Technology Transfer and Advancement Act, the Agency is directed to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) developed or adopted by voluntary consensus standard bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires that Agency to provide Congress, through the OMB, an explanation of the reasons for not using such standards.

This rule does not establish any new technical standards and thus, the Agency has no need to consider the use of voluntary consensus standards in developing this final rule.

XIII. Executive Order 13132 Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that impose substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This action does not have federalism implication. It will not have a substantial direct effect on 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, because it affects only one facility.

Lists of Subjects in 40 CFR Part 261

Environmental Protection, Hazardous Waste, Recycling, Reporting and Recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f)

Dated: June 15, 2001.

Carl E. Edlund,

Director, Multimedia Planning and Permitting Division.

For the reasons set out in the preamble, 40 CFR part 261 is proposed to be 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, and 6938.

2. In Table 1 of Appendix IX of part 261 it is proposed to add the following waste stream in alphabetical order by facility to read as follows:

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

TABLE 1.—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * * * *
Texas Arai Chemical Company	Houston, Texas	Wastewater treatment sludge EPA Hazardous Waste No. F006 generated at a maximum annual rate of 186 cubic yards per calendar year after (publication date of the final rule) and disposed of in a Subtitle D landfill. Texas Arai must implement a testing program that meets the following conditions for the exclusion to be valid: (1) Delisting Levels: All concentrations for the following constituents must not exceed the following levels (mg/l). The wastewater treatment sludge constituents must be measured in the waste leachate by the method specified in 40 CFR 261.24.

TABLE 1.—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(A) Wastewater treatment sludge: (i) Inorganic Constituents: Arsenic—0.163; Barium—100; Chromium—5.0; Cobalt—39.3; Copper—130; Manganese—91.7; Nickel—49.3; Tin—393.0 ; Zinc—489.0. (ii) Organic Constituents: Acetonitrile—21.3; Allyl Chloride—0.00435; Carbon Disulfide—2.94; bis(2-ethylhexylphthalate—4.88; Ethylbenzene—3.33; Methylene Chloride—3.95; Xylenes—104.0. (2) Verification Testing Requirements: Texas Arai must perform sample collection and analyses, including quality control procedures, according to SW–846 methodologies. (A) Required Testing: (i) Texas Arai must collect and analyze at least four composite samples of the wastewater treatment sludge quarterly for a period of one year. The samples must be analyzed for constituents listed in Paragraph 1. (ii) After paragraph (3)(A)(i) has been completed, Texas Arai must collect and analyze at least one composite sample of the wastewater treatment sludge annually. (3) Changes in Operating Conditions: If Texas Arai significantly changes the process which generate(s) the waste(s) and which may or could affect the composition or type waste(s) generated as established under Paragraph(1) (by illustration, but not limitation, change in equipment or operating conditions of the treatment process), Texas Arai must notify the EPA in writing and may no longer manage the waste generated from the new process as nonhazardous until the waste meet the delisting levels set in Paragraph (1) and it has received written approval to do so from EPA. (4) Data Submittals: Texas Arai must submit or maintain, as applicable, the information described below. If Texas Arai fails to submit the required data within the specified time or maintain the required records on-site for the specified time, EPA, at its discretion, will consider this sufficient basis to reopen the exclusion as described in Paragraph 6. Texas Arai must: (A) Submit the data obtained through Paragraph 3 to Mr. William Gallagher, Chief, Region 6 Delisting Program, EPA, 1445 Ross Avenue, Dallas, Texas 75202–2733, Mail Code (6PD-O) within the time specified. (B) Compile records of operating conditions and analytical data from Paragraph (3), summarized, and maintained on-site for a minimum of five years. (C) Furnish these records and data when EPA or the State of Texas request them for inspection. (D) Send along with all data a signed copy of the following certification statement, to attest to the truth and accuracy of the data submitted: ''Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code, which include, but may not be limited to, 18 U.S.C. § 1001 and 42 U.S.C. § 6928), I certify that the information contained in or accompanying this document is true, accurate, and complete.'' As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate, and complete. If any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of waste will be void as if it never had effect or to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion.''

TABLE 1.—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(5) *Reopener Language* (A) If, anytime after disposal of the delisted waste, Texas Arai possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or ground water monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified for the delisting verification testing is at a level higher than the delisting level allowed by the Regional Administrator or his delegate in granting the petition, then the facility must report the data, in writing, to the Regional Administrator or his delegate within 10 days of first possessing or being made aware of that data. (B) If the annual testing of the waste does not meet the delisting requirements in Paragraph 1, Texas Arai must report the data, in writing, to the Regional Administrator or his delegate within 10 days of first possessing or being made aware of that data. (C) If Texas Arai fails to submit the information described in paragraphs (5), (6)(A) or (6)(B) or if any other information is received from any source, the Regional Administrator or his delegate 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. (D) If the Regional Administrator or his delegate determines that the reported information does require Agency action, the Regional Administrator or his delegate will notify the facility, in writing, of the actions the Regional Administrator or his delegate believes are necessary to protect human health and the environment. The proposal shall include a statement of the proposed action and a statement providing the facility with an opportunity to present information as to why the proposed Agency action is not necessary. The facility shall have 10 days from the date of the Regional Administrator or his delegate's action to present such information. (E) Following the receipt of information from the facility described in paragraph (6)(C) or (if no information is presented under paragraph (6)(C) the initial receipt of information described in paragraphs (5), (6)(A) or (6)(B)), the Regional Administrator or his delegate 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 or his delegate's determination shall become effective immediately, unless the Regional Administrator or his delegate provides otherwise. (6) Notification Requirements: Texas Arai must do the following before transporting the delisted waste off-site: Failure to provide this notification will result in a violation of the delisting petition and a possible revocation of the exclusion. (A) Provide a one-time written notification to any State Regulatory Agency to which or through which they will transport the delisted waste described above for disposal, 60 days before beginning such activities. (B) Update the one-time written notification if they ship the delisted waste to a different disposal facility.

* * * * *

[FR Doc. 01–17561 Filed 7–12–01; 8:45 am]
BILLING CODE 6560–50–P

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: Notice of proposed rulemaking.

SUMMARY: The Secretary has made findings as to a condition that can reasonably be determined in some circumstances to be caused by vaccines containing live, oral, rhesus-based rotavirus. Based on these findings, the Secretary proposes to amend the Vaccine Injury Table (Table) by adding to the Table vaccines containing live, oral, rhesus-based rotavirus as a distinct category, with intussusception listed as a covered Table injury. This proposal is based upon the recommendation by the Centers for Disease Control and Prevention (CDC) that Rotashield, the only U.S.-licensed rotavirus vaccine, no longer be administered to infants in the United States based on review of data indicating a strong association between Rotashield and intussusception in the 1 to 2 weeks following vaccination. The Secretary also proposes several additional amendments to the Table described below under **SUPPLEMENTARY INFORMATION**.

DATES: Comments on this proposed rule must be submitted by January 9, 2002. A public hearing on this proposed rule will be held before the end of the public comment period. A separate notice will be published in the **Federal Register** to provide the details of this hearing.

ADDRESSES: Written comments should be addressed to Samuel Shekar, Associate Administrator for Health Professions, Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Parklawn Building, Room 8–05, 5600 Fishers Lane, Rockville, Maryland 20857. All comments received will be available for public inspection and copying at the Office of Planning and Program Development, BHPr, Room 8–67, Parklawn Building, at the above address weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, Medical Director, Division of Vaccine Injury Compensation, BHPr, HRSA, Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443–4198.

SUPPLEMENTARY INFORMATION:

Rotavirus Vaccine

On August 31, 1998, the Food and Drug Administration (FDA) licensed a live, oral, rhesus-based rotavirus tetravelant vaccine for use in infants between the ages of 6 weeks and 1 year. Distribution of the vaccine began on October 1, 1998. Following a review by the Advisory Committee on Immunization Practices (ACIP), the CDC published its rotavirus recommendation in the March 19, 1999, issue of the *Morbidity and Mortality Weekly Report* (MMWR), calling for doses to be administered at 2, 4 and 6 months of age, the first dose to be administered between 6 weeks and 6 months. The series was not to be initiated in children who were 7 months of age or older due to an increased rate of febrile (fever) reactions after the first dose among older infants.

Over the next 8 months, the Secretary's Vaccine Adverse Event Reporting System (VAERS) began receiving reports of intussusception (a type of bowel obstruction that occurs when the bowel folds in on itself) in infants receiving rotavirus vaccine, mostly after the first dose. Based on an analysis of 15 reports, CDC, in the July 16, 1999, issue of the MMWR, recommended that health-care providers and parents postpone use of the rotavirus vaccine. Additional epidemiological studies were undertaken by CDC to determine if there was a true association between the vaccine and intussusception. Also at that time, the manufacturer, in consultation with FDA, voluntarily ceased further distribution of the vaccine. Upon further consideration, and following consultation with CDC officials in preparation for the upcoming ACIP meeting, the manufacturer announced withdrawal of the only U.S.-licensed rotavirus vaccine from the market on October 15, 1999, and requested the immediate return of all doses of the vaccine.

At its October 22, 1999, meeting, the ACIP reviewed scientific data from several sources, including a 19-State case-control study which showed a statistically significant rate of intussusception among recipients of the live, oral, rhesus-based rotavirus vaccine in the 1- to 2-week period following vaccine administration. Beyond 14 days, there did not appear to be more cases than might occur by chance alone. The ACIP concluded that intussusception occurs with significantly increased frequency in the first 14 days following rotavirus administration and withdrew its recommendation for use of the rhesus-based rotavirus vaccine in infants. CDC published the Committee's decision in the November 5, 1999, issue of the MMWR.

As of December 2000, VAERS had received over 100 reports of confirmed and presumptive intussusception cases, 58 of which had onset within 7 days of vaccine receipt. No reports have been received thus far for vaccines administered after the July 1999 MMWR notice. Of the cases reported, approximately one-half required surgical intervention. Nearly all of the remaining cases of bowel obstruction were relieved through barium enema, a radiological procedure used to both diagnose and often rectify the telescoped bowel segment, or resolved without any intervention. At least one death associated with rotavirus vaccine was reported to VAERS.

The general category of rotavirus vaccines was added for coverage under the VICP effective October 22, 1998. Section 2114(e)(2) of the Public Health Service (PHS) Act provides for the inclusion of additional vaccines in the VICP when they are recommended by the CDC for routine administration to children. In compliance with the requirements of the Omnibus Budget Reconciliation Act of 1993, which added a new section 2114(e)(3) to the Act, a vaccine added to the Table through section 2114(e) will be included in the Table, effective when an excise tax to provide funds for they payment of compensation with respect to such vaccines takes effect. This section, codified at 42 U.S.C. 300aa–14(e)(3), read as follows:

> (3) **Effective Date**—A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a)).

The two prerequisites for adding rotavirus vaccine to the VICP were satisfied by enactment of Public Law 105–77, the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, which set