Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: June 15, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 05–12582 Filed 6–23–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–7925–2]

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

AGENCY: Environmental Protection Agency.

ACTION: Proposed amendment and request for comment.

SUMMARY: The Environmental Protection Agency (EPA, also ''the Agency'' or ''we'' in this preamble) is proposing to modify an exclusion (or ''delisting'') from the lists of hazardous waste previously granted to Nissan North America, Inc. (Nissan) in Smyrna, Tennessee.

This action responds to a petition for amendment submitted by Nissan to increase the maximum annual volume covered by its current exclusion for a F019 listed hazardous waste.

The Agency is basing its tentative decision to grant the petition for amendment on an evaluation of specific information provided by the petitioner. This tentative decision, if finalized, would increase the annual volume of waste conditionally excluded from the requirements of the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

DATES: EPA is requesting public comments on this proposed amendment. We will accept comments on this proposal until August 8, 2005. Comments postmarked after the close of the comment period will be stamped ''late.'' These late comments may not be considered in formulating a final decision.

Any person may request a hearing on this tentative decision to grant the petition for amendment by filing a request by July 11, 2005. The request must contain the information prescribed in 40 CFR 260.20(d).

ADDRESSES: Please send two copies of your comments to Daryl R. Himes, South Enforcement and Compliance Section, RCRA Enforcement and Compliance Branch, Waste Management Division, U.S. EPA Region 4, 61 Forsyth Street SW., Atlanta, GA, 30303. Comments may also be sent to Daryl R. Himes via email at *Himes.Daryl@epa.gov.*

Your request for a hearing should be addressed to Narindar M. Kumar, Chief, RCRA Enforcement and Compliance Branch, Waste Division, U.S. Environmental Protection Agency Region 4, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303.

The RCRA regulatory docket for this proposed rule is located at the offices of U.S. EPA Region 4, 61 Forsyth Street SW., Atlanta, GA, 30303, and is available for your viewing from 8:30 a.m. to 5 p.m., Monday through Friday, except on Federal holidays. Please call Daryl R. Himes, at (404) 562–8614 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, please contact Daryl R. Himes at the address above or at (404) 562–8614.

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

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I. Background

A. What Laws and Regulations Give EPA the Authority To Delist Waste?

EPA published amended lists 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. These lists have been amended several times, and are found at 40 CFR 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 40 CFR Part 261 (*i.e.,* ignitability, corrosivity, reactivity, and toxicity), or (2) they meet the criteria for listing contained in 40 CFR 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 that is described in these regulations generally is hazardous, a specific waste from an individual facility meeting the listing description may not be.

For this reason, 40 CFR 260.20 and 260.22 provide an exclusion procedure which allows a person to demonstrate that a specific listed waste from a particular generating facility should not be regulated as a hazardous waste, and should, therefore, be delisted.

According to 40 CFR 260.22(a)(1), in order to have these wastes excluded a petitioner must first show that wastes generated at its facility do not meet any of the criteria for which the wastes were listed. The criteria which we use to list wastes are found in 40 CFR 261.11. An explanation of how these criteria apply to a particular waste is contained in the background document for that listed waste.

In addition to the criteria that we considered when we originally listed the waste, we are also required by the provisions of 40 CFR 260.22(a)(2) to consider any other factors (including additional constituents), if there is a reasonable basis to believe that these factors could cause the waste to be hazardous.

In a delisting petition, the petitioner must demonstrate that the waste does not exhibit any of the hazardous waste characteristics defined in Subpart C of

40 CFR Part 261 (*i.e.,* ignitability, corrosivity, reactivity, and toxicity), and must present sufficient information for EPA to determine whether the waste contains any other constituents at hazardous levels.

A generator remains obligated under RCRA to confirm that its waste remains nonhazardous based on the hazardous waste characteristics defined in Subpart C of 40 CFR Part 261 even if EPA has delisted its waste.

We also define residues from the treatment, storage, or disposal of listed hazardous wastes and mixtures containing listed hazardous wastes as hazardous wastes. (*See* 40 CFR 261.3(a)(2)(iv) and (c)(2)(i), referred to as the ''mixture'' and ''derived-from'' rules, respectively.) These wastes are also eligible for exclusion but remain hazardous wastes until delisted.

B. What Waste Is Currently Delisted at Nissan?

Nissan operates a light-duty vehicle manufacturing facility in Smyrna, Tennessee. As a result of Nissan's use of aluminum as a component of its automobile bodies, Nissan generates a sludge meeting the listing definition of F019 at 40 CFR 261.31.

On October 12, 2000, Nissan petitioned EPA under the provisions in 40 CFR 260.20 and 260.22 to exclude the F019 sludge, discussed above, from hazardous waste regulation.

In support of its October 12, 2000, petition, Nissan submitted sufficient information to EPA to allow us to determine that the waste was not hazardous based upon the criteria for which it was listed and that no other hazardous constituents were present in the waste at levels of regulatory concern.

A full description of the Agency's evaluation of the 2000 Nissan petition is contained in the Proposed Rule and Request for Comments published in the **Federal Register** on November 19, 2001, (223 FR 57918).

After evaluating public comment on the Proposed Rule, we published a final decision in the **Federal Register** on June 21, 2002, (67 FR 41287) to exclude the Nissan F019 wastewater treatment sludge from the list of hazardous wastes found in 40 CFR 261.31.

EPA's final decision in 2002 was conditioned on the volume of waste identified in the 2001 Nissan petition. Specifically, the exclusion granted by EPA is limited to a maximum annual volume of 2400 cubic yards. Any additional waste volume in excess of this limit generated by Nissan in a calendar year was to have been managed as hazardous waste.

C. What Does Nissan Request in Its Petition for Amendment?

As a result of an increase in wastewater treatment sludge filter cake production associated with an increase in vehicle production, Nissan petitioned EPA on February 3, 2004, for an amendment to its June 21, 2002, final exclusion. In its petition, Nissan requested an increase in the maximum annual waste volume that is covered by its exclusion from 2400 cubic yards to 3500 cubic yards.

II. Disposition of Petition Amendment

A. What Information Did Nissan Submit to Support Its Petition for Amendment?

The exclusion which we granted to Nissan on June, 21, 2002, is a conditional exclusion. In order for its exclusion to have remained effective, Nissan has performed verification testing on its delisted F019 waste water treatment sludge. Constituents tested for by the required verification testing were previously identified for Nissan by EPA in the June 21, 2002, final exclusion. The constituents identified were those detected in initial analysis of Nissan's F019 waste water treatment sludge.

Nissan has submitted its verification testing results to EPA as required in the June 21, 2002, Final Rule. A summary of the maximum values detected from samples of Nissan's F019 waste for each of Nissan's verification testing constituents are presented in Table 1 below. The values presented were identified from a review of the verification testing results as well as the initial testing results which were performed to identify the verification testing constituents.

TABLE 1.—MAXIMUM TOTAL CONSTITUENT AND LEACHATE CONCENTRATIONS [1] WWTP FILTER CAKE

Inorganic constituents	Total constituent concentration (mg/kg)	TCLP leachate concentration (mg/l)
Barium	6600.0	0.18
Cadmium	6.0	<0.010
Chromium	160.00	<0.050
Lead	390.0	<0.0050
Nickel	4600	<0.050
4-Methyl-phenol (ρ-cresol)		0.31
Bis (2-ethylhexyl) phthalate		<0.050
Di-n-octyl phthalate		<0.050
Cyanide	3.2	0.0095

[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.

< Denotes that the constituent was not detected at the concentration specified in the table.

The verification testing program specified by the current exclusion for Nissan requires leachate constituent analysis for the metal and organic constituents. In addition, analysis for totals levels for each of the metal constituents as well as cyanide is also currently required.

B. How did EPA evaluate risk for the November 19, 2001, Nissan petition and this proposed amendment?

In the rule proposed on November 19, 2001, and this proposed amendment, EPA has determined the delisting levels for Nissan's F019 waste water treatment plant sludge based on the following: (1) EPA Composite Model for Leachate Migration with Transformation Products (EPACMTP model) as used in EPA, Region 6's Delisting Risk Assessment Software (DRAS); (2) use of DRAS-calculated levels based on Safe Drinking Water Act Maximum Contaminant Levels (MCLs) if more conservative delisting levels would be obtained; (3) use of the Multiple Extraction Procedure (MEP), SW–846 Method 1320, to evaluate the long-term resistance of the waste to leaching in a landfill; (4) setting limits on total concentrations of constituents in the waste.

C. What Conclusion Did EPA Reach?

EPA believes that the information provided by Nissan provides a reasonable basis to grant Nissan's petition for an amendment to its current delisting. We, therefore, propose to grant Nissan an amendment for an increase in waste volume. The data submitted to support the petition and the Agency's evaluation show that the constituents in the Nissan wastewater treatment sludge filter cake are below health-based levels used by the Agency for delisting decision-making even at the increased maximum annual waste volume of 3500 cubic yards.

For this delisting determination, we used information gathered to identify plausible exposure routes (*i.e.*, groundwater, surface water, air) for hazardous constituents present in the petitioned waste. We determined that disposal in a Subtitle D landfill is the most reasonable, worst-case disposal scenario for Nissan's petitioned waste. We applied the Delisting Risk Assessment Software (DRAS) described above to predict the maximum allowable concentrations of hazardous constituents that may be released from the petitioned waste after disposal, and we determined the potential impact of the disposal of Nissan's petitioned waste on human health and the environment. In assessing potential risks to groundwater, we used the increased maximum waste volume and the maximum measured or calculated leachate concentrations as inputs to the DRAS program to estimate the constituent concentrations in the groundwater at a hypothetical receptor well downgradient from the disposal site. Using an established risk level, the DRAS program can back-calculate receptor well concentrations (referred to as a compliance-point concentration) using standard risk assessment algorithms and Agency health-based numbers.

EPA Region 4 generally defines acceptable risk levels for the delisting program as wastes with an excess cancer risk of no more than 1×10^{-5} and a hazard quotient of no more than 1.0 for individual constituents.

Using the maximum compliance-point concentrations and the EPACMTP fate and transport modeling factors, the DRAS further back-calculates the maximum waste constituent concentrations which would not exceed the compliance-point concentrations in groundwater.

The Agency believes that the EPACMTP fate and transport model represents a reasonable worst-case scenario for possible groundwater 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 the RCRA Subtitle C program. The use of a 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 increased waste volume requested in the petition 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). As in the groundwater 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. In most cases, because a delisted waste is no longer subject to hazardous waste control, the Agency is generally unable to predict, and does not presently control, how a petitioner will manage a waste after it is excluded. Therefore, we believe that it is inappropriate to consider extensive site-specific factors when applying the fate and transport model.

As a condition of Nissan's current delisting, Nissan must continue to test for a list of verification constituents. Based on the increased waste volume requested in the petition, new proposed maximum allowable leachate concentrations and maximum allowable total constituent concentrations (as explained below) 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. The maximum allowable concentration of the verification constituents, both in leachate and totals levels, were recalculated for each of the current verification constituents. These concentration limits are shown in Table 2 below.

TABLE 2.—MAXIMUM ALLOWABLE CONCENTRATION OF CONSTITUENTS IN LEACHATE OR IN WASTE [1]

Constituent	Maximum allowable leachate concentration (mg/l)	Maximum allowable total concentration (mg/kg)
Barium	1.00e+02	6.16e+07
Cadmium	1.00e+00	6.43e+05
Chromium	5.00e+00	1.93e+09
Lead	5.00e+00	4.56e+05
Nickel	6.07e+01	2.57e+07
Cyanide	7.73e+00	2.57e+07
Bis(2-ethylhexyl)phthalate	6.01e−01	.....
ρ-Cresol	7.66e+00	.....
Di-n-octyl phthalate	7.52e−02	.....

[1]The term "e" in the table is a variation of "scientific notation" in base 10 exponential form and is used in this table because it is a convenient way to represent very large or small numbers. For example, 3.00e–03 is equivalent to 3.00×10^{-3} and represents the number 0.003.

The Final Rule published in the **Federal Register** on June 21, 2002, (67 FR 41287) included maximum allowable total concentration limits for each of the inorganic constituents and cyanide for which Nissan would be required to perform verification testing results. Upon a comparative review of the maximum total constituent levels analyzed for as shown in Table 1 to the maximum allowable levels of these constituents as calculated by the DRAS model, EPA is proposing to remove the requirement from the June 21, 2002, Final Rule which requires Nissan to

analyze its verification samples for the currently specified total values. This proposal is being made based upon a comparison made by EPA between the results of such totals analysis shown in Table 1 as compared to the totals levels calculated for these constituents by the DRAS model in Table 2. The maximum allowable verification levels for total constituent levels shown in Table 2 are in excess of an order of magnitude of three (10^3) times greater than the results of the sample analysis performed by Nissan for totals values shown in Table 1.

III. Conditions for Exclusion

A. What Are the Maximum Allowable Concentrations of Hazardous Constituents?

The following table (Table 3) summarizes the maximum allowable constituent concentrations (delisting levels) which EPA is proposing for Nissan's waste. We recalculated these delisting levels for each constituent that is part of Nissan's current delisting using the DRAS and the increased maximum annual waste volume of 3500 cubic yards. These proposed delisting levels were derived from the health-based calculations performed by the DRAS program using either strict health-based levels or MCLs, or from Toxicity Characteristic regulatory levels, whichever resulted in a lower (*i.e.*, more conservative) concentration.

TABLE 3.—MAXIMUM ALLOWABLE CONCENTRATION OF CONSTITUENTS IN LEACHATE OR IN WASTE [1]

Constituent	Maximum allowable leachate concentration (mg/l)
Barium	1.00e+02
Cadmium	1.00e+00
Chromium	5.00e+00
Lead	5.00e+00
Nickel	6.07e+01
Cyanide	7.73e+00
Bis(2-ethylhexyl)phthalate	6.01e−01
ρ-Cresol	7.66e+00
Di-n-octyl phthalate	7.52e−02

[1]The term "e" in the table is a variation of "scientific notation" in base 10 exponential form and is used in this table because it is a convenient way to represent very large or small numbers. For example, 3.00e–03 is equivalent to 3.00×10^{-3} and represents the number 0.003.

The current maximum allowable constituent concentrations (delisting levels) for Nissan as found in 40 CFR 261 Appendix IX, Table 1, are specified as leachate concentrations for inorganic and organic constituents and cyanide, and as total constituent concentrations for inorganic constituents for reasons set forth previously in the Proposed Rule published in the **Federal Register** on November 19, 2001 (223 FR 57918).

B. How Frequently Must Nissan Test the Waste and How Must It Be Managed Until It Is Disposed?

Nissan must continue to test and manage its waste according to the conditions set forth in its current delisting. We are not proposing in this amendment to change the method of sample collection, the frequency of sample analyses or the waste holding procedures currently specified in EPA's final decision in the **Federal Register** on June 21, 2002, (67 FR 41287), except the total constituent analyses, which no longer will be required.

C. What Must Nissan Do If the Process Changes?

We are not proposing to change the conditions regarding process changes as set forth in EPA's final decision in the **Federal Register** on June 21, 2002, (67 FR 41287).

D. What Data Must Nissan Submit?

We are not proposing to change the data Nissan is required to submit as specified in EPA's final decision in the **Federal Register** on June 21, 2002, (67 FR 41287).

E. What Happens If Nissan Fails to Meet the Conditions of the Exclusion?

We are not proposing to change the reopener language Nissan is required to comply with as specified in EPA's final decision in the **Federal Register** on June 21, 2002, (67 FR 41287).

IV. Effect on State Authorizations

This proposed amendment, if promulgated, would be issued under the Federal RCRA delisting program. States, however, may impose more stringent regulatory requirements than EPA pursuant to Section 3009 of RCRA. These more stringent requirements may include a provision which prohibits a Federally-issued exclusion from taking effect in the State. Because a petitioner's waste may be regulated under a dual system (*i.e.*, both Federal (RCRA) and State (RCRA) or State (non-RCRA) programs), petitioners are urged to contact State regulatory authorities to determine the current status of their wastes under the State laws.

Furthermore, some States are authorized to administer a delisting program in lieu of the Federal program (*i.e.*, to make their own delisting decisions). Therefore, this proposed amendment, if promulgated, may not apply in those authorized States, unless it is adopted by the State. If the petitioned waste is managed in any State with delisting authorization, Nissan must obtain delisting authorization from that State before the waste may be managed as nonhazardous in that State.

V. Effective Date

EPA is today making a tentative decision to grant Nissan's petition for amendment. This proposed rule, if made final, will become effective immediately upon such final publication. 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. That is the case here, because this rule, if finalized, would reduce the existing requirements for a facility generating hazardous wastes. In light of the unnecessary hardship and expense that would be imposed on this petitioner by an effective date six months after publication and the fact that a six-month deadline is not necessary to achieve the purpose of Section 3010, EPA believes that this exclusion should be effective

immediately upon final publication. These reasons also provide a basis for making this rule effective immediately, upon final publication, under the Administrative Procedures Act, 5 U.S.C. 553(d).

VI. Administrative Requirements

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 particular 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, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 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 communities of 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, 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(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) 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. 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.*).

VII. Public Comments

A. How May 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 the Chief, North Section, RCRA Enforcement and Compliance Branch, U.S. Environmental Protection Agency Region 4, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303. Send a third copy to Mr. Mike Apple, Director, Division of Solid Waste Management, Tennessee Department of Environment and Conservation, 5th Floor, L&C Tower, 401 Church Street, Nashville, Tennessee 37243–1535. You should identify your comments at the top with this regulatory docket number: R$DLP–0401–Nissan.

You should submit requests for a hearing to Narrindar M. Kumar, Chief, RCRA Enforcement and Compliance Branch, Waste Division, U.S. Environmental Protection Agency Region 4, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303.

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 U.S. Environmental Protection Agency Region 4, Atlanta Federal Center, 61 Forsyth Street SW., Atlanta, Georgia 30303.

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 (404) 562–8614 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.

VIII. Regulatory Impact

Under Executive Order 12866, the 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 the EPA's hazardous waste management regulations. This reduction would be achieved by excluding waste generated at a specific facility from the EPA's lists of hazardous wastes, thus enabling a facility to manage its waste as nonhazardous.

Because there is no additional impact from this 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.

IX. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, whenever an agency is required to publish a general notice 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 (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 the EPA's hazardous waste regulations and would be limited to one facility. Accordingly, the EPA hereby certifies that this proposed regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities. Therefore, this regulation does not require a regulatory flexibility analysis.

X. Paperwork Reduction Act

Information collection and recordkeeping 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 (Pub. L. 96 511, 44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2050 0053.

XI. 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, the 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 the EPA rules under section 205 of the UMRA, the EPA must identify and consider alternatives. The alternatives must include 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 the 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 the EPA's 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 this 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.

XII. 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 the 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 EPA 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 EPA. 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.

XIII. 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, the 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, the 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 the 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 the EPA to develop an effective process permitting elected and other representatives of Indian tribal governments to have ''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.

XIV. National Technology Transfer and Advancement Act

Under section 12(d) of the National Technology Transfer and Advancement Act, the EPA 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 the EPA, the Act requires that the EPA 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 EPA has no need to consider the use of voluntary consensus standards in developing this final rule.

XV. Executive Order 13132 Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) requires the 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'' are 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, the EPA may not issue a regulation that has federalism implications, that imposes 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 the 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 EPA 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.

List of Subjects in 40 CFR Part 261

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

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

Dated: June 9, 2005.

Jon D. Johnston,

Acting Director, Waste Management Division, Region 4.

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, and 6938.

2. In Table 1 of appendix IX, part 261 add the following wastestream in alphabetical order by facility to read as follows:

Appendix IX—Wastes Excluded Under Secs. 260.20 and 260.22.

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	* *	* * * *
Nissan North America, Inc	Smyrna, Tennessee	Wastewater treatment sludge (EPA Hazardous Waste No. F019) that Nissan North America, Inc. (Nissan) generates by treating wastewater from the automobile assembly plant located at 983 Nissan Drive in Smyrna, Tennessee. This is a conditional exclusion for up to 3,500 cubic yards of waste (hereinafter referred to as ''Nissan Sludge'') that will be generated each year and disposed in a Subtitle D landfill after [Publication Date of the Final Rule]. Nissan must continue to demonstrate that the following conditions are met for the exclusion to be valid. (1) Delisting Levels: All leachable concentrations for these metals, cyanide, and organic constituents must not exceed the following levels (ppm): Barium—100.0; Cadmium—0.422; Chromium—5.0; Cyanide—7.73, Lead—5.0; and Nickel—60.7; Bis—(2-ethylhexyl) phthalate—0.601; Di-n-octyl phthalate—0.0752; and 4–Methylphenol—7.66. These concentrations must be measured in the waste leachate obtained by the method specified in 40 CFR 261.24, except that for cyanide, deionized water must be the leaching medium. Cyanide concentrations in waste or leachate must be measured by the method specified in 40 CFR 268.40, Note 7. (2) Verification Testing Requirements: Sample collection and analyses, including quality control procedures, must be performed according to SW–846 methodologies, where specified by regulations in 40 CFR parts 260–270. Otherwise, methods must meet Performance Based Measurement System Criteria in which the Data Quality Objectives are to demonstrate that representative samples of the Nissan Sludge meet the delisting levels in Condition (1). Nissan must perform an annual testing program to demonstrate that the constituent concentrations measured in the TCLP extract do not exceed the delisting levels established in Condition (1). If the levels of constituents measured in Nissan's annual testing program do not exceed the levels set forth in Condition (1), then the Nissan Sludge is non-hazardous and must be managed in accordance with all applicable solid waste regulations. If constituent levels in a composite sample exceed any of the delisting levels set forth in Condition (1), the batch of Nissan Sludge generated during the time period corresponding to this sample must be managed and disposed of in accordance with Subtitle C of RCRA. (4) Changes in Operating Conditions: Nissan must notify EPA in writing when significant changes in the manufacturing or wastewater treatment processes are implemented. EPA will determine whether these changes will result in additional constituents of concern. If so, EPA will notify Nissan in writing that the Nissan Sludge must be managed as hazardous waste F019 until Nissan has demonstrated that the wastes meet the delisting levels set forth in Condition (1) and any levels established by EPA for the additional constituents of concern, and Nissan has received written approval from EPA. If EPA determines that the changes do not result in additional constituents of concern, EPA will notify Nissan, in writing, that Nissan must verify that the Nissan Sludge continues to meet Condition (1) delisting levels. (5) Data Submittals: Data obtained in accordance with Condition (2) must be submitted to Narindar M. Kumar, Chief, RCRA Enforcement and Compliance Branch, Mail Code: 4WD–RCRA, U.S. EPA, Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303. The submission is due no later than 60 days after taking each annual verification samples in accordance with delisting Conditions (1) through (7). Records of analytical data from Condition (2) must be compiled, summarized, and maintained by Nissan for a minimum of three years, and must be furnished upon request by EPA or the State of Tennessee, and made available for inspection. Failure to submit the required data within the specified time period or maintain the required records for the specified time will be considered by EPA, at its discretion, sufficient basis to revoke the exclusion to the extent directed by EPA. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12).

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

Facility	Address	Waste description
		(6) Reopener Language: (A) If, at any time after disposal of the delisted waste, Nissan possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or groundwater monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified in the delisting verification testing is at a level higher than the delisting level allowed by EPA in granting the petition, Nissan must report the data, in writing, to EPA within 10 days of first possessing or being made aware of that data. (B) If the testing of the waste, as required by Condition (2)(B), does not meet the delisting requirements of Condition (1), Nissan must report the data, in writing, to EPA within 10 days of first possessing or being made aware of that data. (C) Based on the information described in paragraphs (6)(A) or (6)(B) and any other information received from any source, EPA will make a preliminary determination as to whether the reported information requires that EPA take 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 EPA determines that the reported information does require Agency action, EPA will notify the facility in writing of the action believed necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing Nissan with an opportunity to present information as to why the proposed action is not necessary. Nissan shall have 10 days from the date of EPA's notice to present such information. (E) Following the receipt of information from Nissan, as described in paragraph (6)(D), or if no such information is received within 10 days, EPA will issue a final written determination describing the Agency actions that are necessary to protect human health or the environment, given the information received in accordance with paragraphs (6)(A) or (6)(B). Any required action described in EPA's determination shall become effective immediately, unless EPA provides otherwise. (7) Notification Requirements: Nissan must provide a one-time written notification to any State Regulatory Agency in a State to which or through which the delisted waste described above will be transported, at least 60 days prior to the commencement of such activities. Failure to provide such a notification will result in a violation of the delisting conditions and a possible revocation of the decision to delist.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

45 CFR Part 61

RIN 0906–AA46

Office of the Secretary, Health Care Fraud and Abuse Data Collection Program: Reporting of Final Adverse Actions; Correction

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Proposed correction amendment.

SUMMARY: This document proposes a correction to the final regulations, which were published in the **Federal Register** on October 26, 1999 (64 FR 57740). These regulations established a national health care fraud and abuse data collection program for the reporting and disclosing of certain adverse actions taken against health care providers, suppliers and practitioners, and for maintaining a data base of final adverse actions taken against health care providers, suppliers and practitioners. An inadvertent error appeared in the text of the regulations concerning the definition of the term ''any other negative action or finding.'' As a result, we are proposing to correct 45 CFR 61.3, Definitions, to assure the technical correctness of these regulations.

DATES: To assure consideration, public comments must be mailed and delivered to the address provided below by no later than 5 p.m., July 25, 2005.

ADDRESSES: Please mail or deliver your written comments to the following address: Department of Health and Human Services, Office of Inspector General, Attention: OIG–46–CA2, 330 Independence Avenue, SW., Room 5246, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, OIG Regulations Officer Office of External Affairs, (202) 619–0089.

SUPPLEMENTARY INFORMATION: The HHS Office of Inspector General (OIG) issued final regulations on October 26, 1999 (64 FR 57740) that established a national health care fraud and abuse data collection program—the Healthcare Integrity and Protection Data Bank (HIPDB)—for the reporting and disclosing of certain final adverse actions taken against health care providers, suppliers and practitioners, and for maintaining a data base of final adverse actions taken against health care providers, suppliers and practitioners. The final rule established a new 45 CFR part 61 to implement the requirements for reporting of specific data elements to, and procedures for obtaining information from, the HIPDB. In that final rule, an inadvertent error appeared in § 61.3—the definitions section of the regulations—and is now being proposed for correction.

Section 61.3 expanded on previous regulatory definitions and provided additional examples of the scope of various terms set fort in the statute. On page 57755 of the preamble, summarizing the various revisions being made to the final rule, we indicated that with respect to the definition for the term ''any other negative action or finding'' there are certain kinds of actions or findings that would not meet the intent of the statute and *not* be