approved under OMB control number 0910–0139.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. We have determined that this proposed rule does not contain policies 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. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

X. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Jacobs, G., ''Validation of the Radiation Sterilization of Pharmaceuticals.'' In: J. Agalloco and F. J. Carleton (eds.), *Validation of Pharmaceutical Processes* (3rd Ed.) Informa USA, New York, 2007.
2. Microbiology Sub-Committee, Radiation Sterilization Task Force, Parenteral Drug Association, Technical Report No. 11, ''Sterilization of Parenterals by Gamma Radiation,'' *Journal of Parenteral Science and Technology,* 42 (3S), 1988, available at: *https://store.pda.org/ProductCatalog/Product.aspx?ID=1170.*
3. United States Pharmacopeial Convention (USP 40), Radiation Sterilization <1229.10>, 2017.
4. United States Pharmacopeial Convention (USP 40), Sterilization of Compendial Articles <1229>, 2017.
5. FDA Guidance for Industry on ''Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice,'' September 2004; available at *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070342.pdf.*
6. United States Pharmacopeial Convention (USP 40), Sterilization and Sterility Assurance of Compendial Articles <1211>, 2017.
7. FDA Drug Safety Communication, ''FDA Requests Label Changes and Single-Use Packaging for Some Over-the-Counter Topical Antiseptic Products to Decrease Risk of Infection,'' November 13, 2013; available at *https://www.fda.gov/Drugs/DrugSafety/ucm374711.htm.*
8. FDA Preliminary Regulatory Impact Analysis, Repeal of Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation; *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 310 be amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262.

■ 2. In § 310.502, revise paragraph (a) introductory text and remove and reserve paragraph (a)(11) to read as follows:

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. An approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act and part 314 of this chapter is required for marketing the following drugs:

* * * * *

(11) [Reserved]

* * * * *

Dated: September 7, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–19845 Filed 9–11–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[EPA–R10–RCRA–2018–0538; SW–FRL–9982–05—Region 10]

Hazardous Waste Management System; Proposed Exclusion for Identifying and Listing Hazardous Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: The Environmental Protection Agency (also, ''the Agency'' or ''we'' in this preamble) is proposing to grant a petition submitted by Sandvik Special Metals (Sandvik), in Kennewick, Washington to exclude (or ''delist'') up to 1,500 cubic yards of F006 wastewater treatment sludge per year from the list of federal hazardous wastes.

The Agency is proposing to grant the petition based on an evaluation of waste-specific information provided by Sandvik. This proposed decision, if finalized, conditionally excludes the petitioned waste from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act.

We conclude that Sandvik's petitioned waste is nonhazardous with respect to the original federal listing criteria and that there are no other factors (including additional constituents) other than those for which the waste was listed that would warrant retaining the waste as a hazardous waste. Subject to state-only requirements within the state of Washington, or federally-authorized or state-only requirements in other states where the subject wastes may be disposed of, Sandvik's petitioned waste may be disposed of in a Subtitle D landfill which is permitted, licensed, or registered by a State to manage industrial solid waste.

DATES: Comments must be received on or before October 12, 2018. Requests for an informal hearing must reach the EPA by September 27, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–RCRA–2018–0538 by one of the following methods:

• *www.regulations.gov:* Follow the on-line instructions for submitting comments.

• *Mail:* To Dr. David Bartus, Office of Air and Waste, EPA, Region 10, 1200 6th Avenue, Suite 155, OAW–150, Seattle, Washington 98101.

• *Hand Delivery:* To Dr. David Bartus, Office of Air and Waste, EPA, Region 10, 1200 6th Avenue, Suite 155, OAW–150, Seattle, Washington 98101. Such deliveries are only accepted during normal hours of operation. Please contact David Bartus at (206) 553–2804.

Instructions: Direct your comments to Docket ID No. EPA–R10–RCRA–2018–0538. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any physical media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Any person may request an informal hearing on this proposed decision by filing a request with Timothy Hamlin, Director, Office of Air and Waste, EPA, Region 10, 1200 6th Ave., Suite 155, OAW–150, Seattle, Washington 98101. The request must contain the information prescribed in 40 Code of Federal Regulations CFR 260.20(d).

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information may not be publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the RCRA Records Center, 16th floor, U.S. EPA, Region 10, 1200 6th Avenue, Suite 155, OAW–150, Seattle, Washington 98101. This facility is open from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. We recommend you telephone David Bartus at (206) 553–2804 before visiting the Region 10 office. The public may copy material from the regulatory docket at 15 cents per page.

FOR FURTHER INFORMATION, CONTACT: Dr. David Bartus, EPA, Region 10, 1200 6th Avenue, Suite 155, OAW–150, Seattle, Washington 98070; telephone number: (206) 553–2804; fax number (206) 553–8509; email address: *bartus.dave@epa.gov*.

As discussed in Section V below, the Washington State Department of Ecology is evaluating Sandvik's petition under state authority. Information on Ecology's action may be found at *https://fortress.wa.gov/ecy/publications/SummaryPages/1804023.html*.

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

I. Overview Information

The EPA is proposing to grant the petition submitted by Sandvik Special Metals (Sandvik) located in Kennewick, Washington to exclude or delist an annual volume of up to 1,500 cubic yards of F006 wastewater treatment sludge from the lists of hazardous waste set forth in 40 Code of Federal Regulations CFR 261.31. Sandvik claims that the petitioned waste does not meet the criteria for which the EPA listed it, and that there are no additional constituents or factors which could cause the waste to be hazardous.

Based on our review described in section III, we agree with the petitioner that the waste is nonhazardous. We reviewed the description of the process which generates the waste and the analytical data submitted by Sandvik. We believe that the petitioned waste does not meet the criteria for which the waste was listed, and that there are no other factors which might cause the waste to be hazardous.

II. Background

A. What is a listed waste?

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 § 3001 of Resource Conservation and Recovery Act (RCRA). The EPA has amended this list several times and published it in 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 part 261 (that is, ignitability, corrosivity, reactivity, and toxicity) or (2) they meet the criteria for listing contained in § 261.11(a)(2) or (3).

B. What is a delisting petition?

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

A procedure to exclude or delist a waste is provided in 40 CFR 260.20 and 260.22 which allows a person or a facility to submit a petition to the EPA or to an authorized state demonstrating

that a specific waste from a particular generating facility is not hazardous.[1]

In a delisting petition, the petitioner must show that a waste does not meet any of the criteria for listed wastes in 40 CFR 261.11 and that the waste does not exhibit any of the hazardous waste characteristics of ignitability, reactivity, corrosivity, or toxicity. The petitioner must present sufficient information for us to decide whether any factors in addition to those for which the waste was listed warrant retaining it as a hazardous waste. (See § 260.22, 42 U.S.C. 6921(f) and the background documents for the listed wastes.)

If a delisting petition is granted, the generator remains obligated under RCRA to confirm that the waste remains nonhazardous according to the conditions of the delisting.

C. What factors must EPA consider in deciding whether to grant a delisting petition?

In reviewing this petition, we considered the original listing criteria and the additional factors required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). See § 222 of HSWA, 42 U.S.C. 6921(f), and 40 CFR 260.22(d)(2)–(4). We evaluated the petitioned waste against the listing criteria and factors cited in § 261.11(a)(2) and (3).

Besides considering the criteria in 40 CFR 260.22(a), 261.11(a)(2) and (3), 42 U.S.C. 6921(f), and in the background documents for the listed wastes, the EPA must consider any factors (including additional constituents) other than those for which we listed the waste if these additional factors could cause the waste to be hazardous.

Our proposed decision to grant the petition to delist the waste from Sandvik's Kennewick, Washington facility is based on our evaluation of the waste for factors or criteria which could cause the waste to be hazardous. These factors included: (1) Whether the waste is considered acutely toxic; (2) the toxicity of the constituents; (3) the concentration of the constituents in the waste; (4) the tendency of the constituents to migrate and to bioaccumulate; (5) the persistence in the environment of any constituents once released from the waste; (6) plausible and specific types of management of the petitioned waste; (7) the quantity of waste produced; and (8) waste variability.

The EPA must also consider as hazardous wastes mixtures containing listed hazardous wastes and wastes derived from treating, storing, or disposing of listed hazardous waste. See 40 CFR 261.3(a)(2)(iv) and (c)(2)(i), called the ''mixture'' and ''derived-from'' rules, respectively. Mixture and derived-from wastes are also eligible for exclusion but remain hazardous until excluded.

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

A. What waste did Sandvik petition the EPA to delist?

On April 27, 2018, Sandvik petitioned the EPA to exclude an annual volume of up to 1,500 cubic yards of F006 wastewater treatment sludges generated at its facility located in Kennewick, Washington from the list of hazardous wastes contained in 40 CFR 261.31. F006 is defined in § 261.31 as ''Wastewater treatment sludges from electroplating operations . . .'' Sandvik claims that the petitioned waste does not meet the criteria for which F006 was listed (*i.e.,* cadmium, hexavalent chromium, nickel and complexed cyanide) and that there are no other factors which would cause the waste to be hazardous.

B. How does Sandvik generate the waste?

Sandvik Special Metals fabricates specialty titanium and zirconium tubing for the aeronautical, medical and nuclear industries. The filter cake waste material that is the subject of this delisting action is the combined end waste from the wastewater treatment facility (WWTF) that manages F006 chemical etching wastes, and a separate coolant process waste stream associated with Sandvik's manufacturing process. A detailed description of the processes which contribute to the filter cake, including the wastewater treatment and the manufacturing processes, associated alloys and process materials, is provided below.

Titanium and zirconium alloys are the main raw materials for the manufacturing process, with titanium being used for most products and zirconium being used only on special orders for the nuclear industry. In recent years, zirconium accounted for less than one percent of the total production, however, zirconium has accounted for up to 10 to 20 percent of the production volume historically. The manufacturing processes meet strict industry standards for Sandvik customers and are consistent at the Kennewick facility.

The standard tube making process for titanium (Ti) and zirconium (Zr) alloyed tubing includes three main steps. See Figure 1 in Sandvik's delisting petition. The alloys used in the process arrive at the Kennewick facility in the form of large diameter rough tubing (either extrusions or Trex [which is an extrusion that has been reduced once]) from one of two suppliers, Sandvik SZ in Sweden or ATI in Oregon. In the first tube-making process, the extrusions or Trex go through multiple cold pilger steps to reduce the diameter size of the tubing into seamless hollow metal tubing. The cold pilgering process uses roll dies (presses) and a tapered mandrel (the rod that supports the inside of the tube during formation) to reduce the size of the tubing cross section. A fatty acid coolant/lubricant is used to manage heat generation during the process. The number of cold pilgering steps is dependent on the available starting materials and final tube size. After each cold pilger step, the interior of the tube is cleaned in a hot alkaline solution to remove the fatty acid coolant/lubricant used in the forming process, resulting in the generation of an alkaline rinsing solution that is discharged to the WWTF and a small amount of used fatty acid coolant/lubricant, which is pumped to an underground storage tank and then batch transferred to the WWTF.

The second step in the tube forming process is a high temperature anneal step performed to relieve stress on the metal that can make it brittle after cold forming. Annealing also improves the homogeneity of the metal and can improve the ductile and toughness properties. No waste is generated during the annealing process.

During the third step, after annealing, the hollows, or final tubes are rotary straightened and cleaned in the hot alkaline solution again to remove the straightening lubrication. The cleaned hollows are open dip etched in an acidic solution to remove a small amount of metal from both the outer diameter (OD) and inner diameter (ID) surfaces. The acidic waste and rinse water from the hollow etch process is discharged to the WWTF. This acid etch step is the basis for application of the F006 listing to Sandvik's WWTF sludge, as discussed in the following section.

If the next pass is to produce a smaller OD or thinner wall hollow, the above three-step process is repeated until the desired sizing is accomplished resulting in a final tube.

[1] Washington State has promulgated regulations at WAC 173–303–910(3) corresponding to the cited federal regulation. However, Washington State has not received final authorization to implement these regulations in lieu of the federal program. As such, they are effective concurrent with 40 CFR 260.20 and 260.22 on a state-only basis.

C. How is Sandvik's waste captured by the F006 listing definition?

The listing definition for F006 waste at 40 CFR 261.31 states that the source definition of F006 wastes include:

Wastewater treatment sludges from electroplating operations except from the following processes: (1) Sulfuric acid anodizing of aluminum; (2) tin plating on carbon steel; (3) zinc plating (segregated basis) on carbon steel; (4) aluminum or zinc-aluminum plating on carbon steel; (5) cleaning/stripping associated with tin, zinc and aluminum plating on carbon steel; and (6) chemical etching and milling of aluminum.

The EPA promulgated an interpretive rule (51 FR 43350 (December 2, 1986)) clarifying the scope of the EPA Hazardous Waste No. F006 contained in the list of hazardous wastes from non-specific sources of Subpart D of Part 261. This interpretive rule established that:

The F006 listing is (and always has been) therefore, inclusive of wastewater treatment sludges from only the following processes: (1) Common and precious metals electroplating, except tin, zinc (segregated basis), aluminum, and zinc-aluminum plating on carbon steel; (2) anodizing, except sulfuric acid anodizing of aluminum; (3) chemical etching and milling, except when performed on aluminum; and (4) cleaning and stripping, except when associated with tin, zinc, and aluminum plating on carbon steel.

Because the Sandvik production process that results in generation of the candidate WWTF sludge includes chemical etching other than that performed on aluminum, Sandvik's WWTF sludge meets the definition of F006 listed waste.

D. How did Sandvik sample and analyze the petitioned waste?

Sandvik conducted a detailed chemical analysis of their WWTF sludge according to a written sampling and analysis plan (SAP), provided as Attachment 2 to the delisting petition. This SAP included the following key elements:

- A description of the manufacturing and wastewater treatment processes relevant to the petitioned waste;
- An initial identification of Constituents of Potential Concern (COPCs) potentially present in the petitioned waste based on manufacturing and wastewater treatment processes;
- Development of sampling strategies to address variations and periodic fluctuations in the manufacturing and wastewater treatment processes, including obtaining representative samples to account for variations of alloys used in the manufacturing process and addition of coolant/lubricant into the filter cake.
- The proposed methodology for evaluating the resulting data with respect to anticipated delisting decision criteria; and
- A Quality Assurance Project Plan (QAPP) documenting the required quality and quantity of the data necessary for decisions based on them to be within an acceptable degree of uncertainty.

Sandvik's SAP identified an initial list of COPCs based on a consideration of constituents included in the F006 hazardous waste listing and present in the manufacturing and wastewater treatment materials and processes. See Section 2 and Table 5 of Attachment 2 in Sandvik's delisting petition. Additionally, the list of COPCs included impurities and other constituents listed in the alloys and in the process and wastewater treatment chemical Safety Data Sheets (SDS).[2] Constituents were then evaluated based on historical detections in the filter cake waste and compared to constituents listed in the following RCRA regulations, as applicable to the Kennewick facility and this specific filter cake waste:

- Constituent for which F006 was listed (40 CFR part 261 Appendix VII; WAC 173–303–082) or listed as a Land Disposal Restriction (LDR) constituent subject to treatment for F006 or identified as a constituent for which an LDR Universal Treatment Standard has been established (40 CFR 268.40 and 268.48; WAC 173–303–140) with the exception of cyanide. Cyanide was not retained as a COPC because there is no documented use of cyanide at the Kennewick facility and it was not detected in historical filter cake samples.
- Constituent has been historically detected in filter cake and was present on the Toxicity Characteristics List (40 CFR 261.24; WAC 173–303–090 Part 8), Hazardous Constituents List (40 CFR part 261 Appendix VIII; WAC 173–303–9905), and/or Groundwater Monitoring List (40 CFR part 264 Appendix IX; WAC 173–303–110(7)).
- According to the alloy composition, constituent could potentially be present in the filter cake and is listed on the Toxicity Characteristics List (40 CFR 261.24; WAC 173–303–090(8)), Hazardous Constituents List (40 CFR part 261 Appendix VIII; WAC 173–303–9905), and/or the Groundwater Monitoring List (40 CFR part 264 Appendix IX; WAC 173–303–110 Part 7).

A constituent was not retained as a COPC if it was not:

- Listed on potentially relevant regulatory lists; or
- There was no documented Kennewick facility use of the constituent, or it was a minor constituent in wastewater treatment material, not detected in historical filter cake samples, or converted to another COPC in the wastewater treatment process (*i.e.,* hydrofluoric acid is present as fluoride in the filter cake).

Based on this analysis, Sandvik's SAP proposed the following list of COPCs: Arsenic; Barium; Cadmium; Chromium (including hexavalent chromium); Cobalt; Copper; Fluoride;[3] Lead; Nickel; Silver; Tin; Vanadium; and Zinc. Details of Sandvik's identification of COPCs can be found in Table 5 in Attachment 2 to the delisting petition.

The objectives of the waste characterization sampling conducted by Sandvik were as follows:

- To supplement the existing historical data set with total and TCLP data for the identified COPCs;
- To collect samples that are representative of process variations that include processing of two different alloy materials (titanium and zirconium) and the periodic addition of the waste coolant/lubricant to the filter cake waste;
- To assess acute toxicity effects of wastes in accordance with the Washington State Department of Ecology's 80–12, Part A protocol,[4] and
- To generate a representative data set that can be used in the Delisting Risk Assessment Software (DRAS) modeling.

To achieve these objectives, Sandvik collected six (6) representative samples over three (3) sampling events that included the following scope of work:

- Each event included the collection of one filter cake sample with the used

[2] SDS constituent reporting requirements are typically ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except chemicals identified as carcinogens which are listed if the concentrations are 0.1% or greater. In addition, chemicals <1% (<0.1% for carcinogens) are reported if they could be released from the product at a concentration that would exceed an established Occupational Safety and Health Administration (OHSA) exposure limit. SDSs are prepared in accordance with OHSA (29 CFR 1910.1200(g)) and the Global Harmonization System.

[3] Fluoride does not meet the criteria set forth in Section 3.1 but is included in the final list of COPCs as requested by the EPA during a 17 April 2017 teleconference.

[4] This sampling requirement is in place to satisfy state-only requirements of Ecology's dangerous waste program. This requirement is considered broader in scope than the federally authorized program.

coolant/lubricant waste stream and one filter cake sample without the used coolant/lubricant waste stream;

- Since titanium raw materials are present at higher weight composition percentages than zirconium, four filter cake samples (two with coolant and two without coolant) events were obtained when only titanium alloys were being run in the manufacturing process; and
- To account for the use of zirconium, two samples (one with coolant and one without coolant) were obtained while zirconium alloys were also being run in the manufacturing process in addition to titanium alloys.[5]

All samples were analyzed for total and TCLP COPCs, where applicable. If chromium was detected at a concentration above the laboratory practical quantitation limit (PQL), a sample from the same sampling event was analyzed for hexavalent chromium. If chromium was not detected above the PQL, no additional testing was performed. This approach to sampling for chromium was used for both total and TCLP sampling.

One sample with the coolant/lubricant and one sample without the coolant/lubricant was analyzed to assess acute toxicity via bioassay as part of the first titanium-only sampling events. This combination of the filter cake production characteristics is expected to be the most conservative choice for bioassay testing, given the higher number of impurities in the titanium alloy. Additional details of Sandvik's waste characterization sampling activities are provided in Attachment 2 to the delisting petition.

D. What were the results of Sandvik's analysis of its waste?

Sandvik provided results of their waste characterization activities in Attachment 3 to the delisting petition entitled ''Sampling Results and Data Evaluation Report.'' As part of its overall delisting petition submission, Sandvik submitted a signed statement certifying that information in the petition, including their submission of waste characterization data and description of the associated sampling and analysis activities, is true, accurate and complete, and the responsibilities of the signatory of the delisting petition. See 40 CFR 260.22(i)(12).

Sandvik conducted its first sampling event on July 31, 2017, followed by two additional sampling events on August 31 and September 25, 2017. Two representative samples of the WWTF filter cake were collected during each event, one with the used coolant/lubricant waste stream and one without, for a total of six filter cake samples. Of these six samples, four were collected when only titanium alloys were being run in the manufacturing process, and two when zirconium was also being run. Each sample was a composite sample collected from four separate locations within each filter cake collection bin used to collect the filter cake following the filter press. Sandvik's delisting petition states that according to facility representatives, the filter cake generation durations and resulting volumes within the filter press during each sampling event were typical for facility operations. Additional details of Sandvik's waste characterization sampling activities can be found in Section 3 of the SAP (Attachment 2 of the delisting petition).

Sandvik performed a quality assurance/quality control review of each laboratory report, with complete results of the data validation review detailed in Appendix C of the SAP. While this review identified one constituent (arsenic) from one sampling round where the data do not fully satisfy the data quality objectives set forth in Sandvik's quality control standards, Sandvik concludes that the data are nevertheless generally suitable for their intended decision-making function. This constituent and sampling round are discussed further below.

Based on the results of filter cake characterization sampling, Sandvik concluded that all constituents other than hexavalent chromium should be retained as constituents of concern for further evaluation. Sandvik's deletion of hexavalent chromium from the list of COPCs is based on hexavalent chromium not being detected in any of the filter cake total or TCLP analysis according to the sampling methodology described above.

Sandvik compared their 2017 waste characterization sampling results to historical total and TCLP results available for several of the COPCs. The range of recent COPC results was consistent with historical results except for fluoride. Historical total fluoride concentrations of 67,500 mg/kg and 42,000 mg/kg from 1991 and 1997, respectively, were several orders of magnitude higher than recent concentrations; the highest recent concentration was 907 mg/kg. Sandvik indicates that it has progressively reduced the amount of etching in its process at the Kennewick facility, which would result in a decline in hydrofluoric acid use and fluoride in the filter cake. In addition, the collection method of the historical samples as well as the production and wastewater treatment system operations at the time of historical sampling are unknown. As a result, the 2017 samples are considered to be more representative of typical conditions for fluoride for current and future operations at the Kennewick facility.

Overall, totals concentrations from the three 2017 sampling events were within the range of historical results. In addition to fluoride, as discussed in the previous paragraph, one 2017 maximum nickel sample (425 mg/kg) exceeded the historical maximum nickel sample of 392 mg/kg. The 2017 totals samples also exceeded historical maximum concentrations for arsenic, barium, chromium, and silver, but none of these constituents had a difference of more than one order of magnitude between the 2017 and historic samples. Because most historical concentrations are from 20 or more years ago and production and collection methods are unknown, the 2017 COPC results obtained from implementation of the SAP were considered more reliable and used for the subsequent data evaluation.

Sandvik also compared the 2017 waste characterization sampling result to the toxicity characteristic (TC) regulatory standard for those waste constituents for which regulatory standards have been established. Based on this comparison, Sandvik concluded that the candidate wastes do not exhibit the toxicity characteristic. Although Sandvik did not explicitly evaluate their candidate wastes for the characteristics of ignitability, reactivity or corrosivity, the EPA agrees that process knowledge provides an adequate demonstration that the wastes in question do not exhibit the enumerated characteristics.

E. How did the EPA evaluate the risk of delisting this waste?

For this delisting determination, we assumed that the waste would be disposed in a Subtitle D landfill and we considered transport of waste constituents through ground water, surface water and air. We evaluated Sandvik's analysis of petitioned waste using the Agency's Delisting Risk Assessment Software (DRAS) to predict the concentration of hazardous constituents that might be released from the petitioned waste and to determine if the waste would pose a threat to human health and the environment. The DRAS software and associated documentation can be found at *www.epa.gov/hw/*

[5] The zirconium product requirements are more sensitive to contamination. As such, the tanks and mills are flushed prior to zirconium production. The titanium product requirements are not as sensitive; therefore, following zirconium production, the same acids and coolant/lubricants are used during titanium production.

hazardous-waste-delisting-risk-assessment-software-dras.

To predict the potential for release to groundwater from landfilled wastes and subsequent routes of exposure to a receptor, the DRAS uses dilution attenuation factors derived from the EPA's Composite Model for leachate migration with Transformation Products. From a release to ground water, the DRAS considers routes of exposure to a human receptor of ingestion of contaminated groundwater, inhalation from groundwater while showering and dermal contact from groundwater while bathing.

From a release to surface water by erosion of waste from an open landfill into storm water run-off, DRAS evaluates the exposure to a human receptor by fish ingestion and ingestion of drinking water. From a release of waste particles and volatile emissions to air from the surface of an open landfill, DRAS considers routes of exposure of inhalation of volatile constituents, inhalation of particles, and air deposition of particles on residential soil and subsequent ingestion of the contaminated soil by a child. The technical support document and the user's guide to DRAS are included in the docket.

Sandvik documented the input parameters used in their DRAS analysis, as summarized below:

TABLE 1—SANDVIK DELISTING DRAS INPUT

DRAS input parameter	Value	Assumptions
Waste Management Unit Type	Landfill	Waste planned for disposal in the Finley Buttes Municipal Landfill, Boardman, Oregon.
Waste Volume—annual generation	1,500 cubic yards/year	Conservative estimation value based on facility-specific information.
Waste Management Unit Active Life	20 years	Selected based on the DRAS default value.
Target risk—carcinogenic risk level	1×10^{-5}	Based on risk ranges in the EPA's RCRA Delisting Technical Support Document (2008).
Target risk—health quotient	1.0	Based on risk ranges in the EPA's RCRA Delisting Technical Support Document (2008).

At a target cancer risk of 1×10^{-5} and a target hazard quotient of 1.0, the DRAS program determined maximum allowable concentrations for each constituent in both the waste and the leachate at an annual waste volume of 1,500 cubic yards. Sandvik used the maximum estimated annual waste volume and the maximum reported total and estimated leachate concentrations as inputs to estimate the constituent concentrations in the ground water, soil, surface water or air. The following table documents the constituent-specific maximum total and TCLP sample results used as input to the DRAS analysis, and the resulting modeling results from DRAS. The EPA notes that it has independently conducted its own DRAS modeling run, and has verified the modeling results documented by Sandvik in its delisting petition.

TABLE 2—SAMPLING DATA AND DRAS MODELING RESULTS

Constituent of concern	Maximum observed concentration [1]		Modeling results			
			Total concentrations		TCLP concentration	
	Total [1] (mg/kg)	TCLP (mg/L) [4]	Limiting concentration (mg/kg) [2]	Limiting pathway [3]	Limiting concentration (mg/L) [2]	Limiting pathway [3]
Arsenic	4.77	0.05 U	9,840	Fish Ingestion	*0.042*	*GW Ingestion.*
Barium	24.1	0.05 U	21,300,000	Fish Ingestion	176	MCL.
Cadmium	15.0	0.05 U	37,100	Fish Ingestion	0.451	MCL.
Chromium	44.3	0.05 U	77,500	Air Particulate Inhalation.	9.54	MCL.
Cobalt	291	0.255	103,000	Air Particulate Inhalation.	1.06	GW Ingestion.
Copper	26.2	0.057	3,790,000	Fish Ingestion	120	MCL.
Fluoride	907	114	1,490,000,000	Soil	194	GW Ingestion.
Lead	11.1	0.05 U	8,870,000	Air Particulate Inhalation.	2.95	MCL.
Nickel	425	0.466	3,870,000	Air Particulate Inhalation.	66.4	GW Ingestion.
Silver	5.76	0.05 U	3,830,000	Fish Ingestion	38.8	GW Ingestion.
Tin	268	0.05 U	14,900,000,000	Soil	192,000,000	GW Ingestion.
Vanadium	1,500	0.05 U	124,000,000	Soil	16.9	GW Ingestion.
Zinc	69.4	0.233	9,810,000	Fish ingestion	992	GW Ingestion.

[1] Maximum concentration obtained during implementation of the 2017 Sampling and Analysis Plan (Geosyntec, 2017).

[2] The Limiting Concentration is the lowest risk-based concentration developed in DRAS for the potential receptor pathways and specified target risk levels. See text in Section IV.C for the EPA's consideration of limiting concentrations exceeding 1,000,000 mg/kg for total concentrations or 1,000,000 mg/L for TCLP concentrations.

[3] The Limiting Pathway is the corresponding potential receptor pathway for the Limiting Concentration.

[4] For detected constituents, the maximum analytical result was used. For non-detect constituents (annotated with a ''U''), the practical quantitation limit (PQL) was used.

[5] **Note:** Italicized cells indicate exceedance of COPC Concentration Input over the Limiting Concentration in the DRAS modeling.

F. What did the EPA conclude about Sandvik's waste?

The maximum reported concentrations of the hazardous constituents found in this waste are presented in the table above. The table also presents the maximum allowable concentrations. Except for the groundwater pathway for arsenic, the concentrations of all constituents in both the waste and the leachate are below the allowable concentrations.

For arsenic, the maximum reported concentration was undetected at a value of 0.05 mg/L, a value slightly higher than the maximum allowable TCLP concentration of 0.042 mg/L. The EPA's review of the corresponding laboratory reports indicate that the laboratory reported sample results from the July 31, 2017 characterization sampling round as non-detect based on a practical quantitation limit of 0.05 mg/L. Subsequent laboratory reports for the August 31, 2017 and October 4, 2017 characterization rounds, however, reported TCLP arsenic results as non-detect at a level of 0.001 mg/L, based on a lower method detection limit rather a practical quantitation limit. Since the total arsenic results for all characterization samples are both low and consistent, ranging from 2.02 to 4.77 mg/kg, the EPA believes that the TCLP arsenic results for the July 31, 2017 results are not likely to be materially different than lower non-detect results for the August 31, 2017 and October 4, 2017 sample results. Also, based on the difference in arsenic concentrations from the totals analysis (detected at low levels) and the TCLP samples (non-detect), arsenic appears to be relatively immobile in the filter cake. Therefore, the EPA concludes that even though the TCLP arsenic data from the August 31, 2017, laboratory report does not explicitly document satisfaction of the 0.042 mg/L TCLP arsenic delisting criterion, the overall data set clearly supports a conclusion that the TCLP arsenic results do not exceed the maximum allowable concentration of 0.042 mg/L from any of the characterization sampling rounds, and that this arsenic data quality issue is not a sufficient basis to disqualify Sandvik's waste from being delisted. If the EPA approves Sandvik's delisting petition, Sandvik must ensure that any required periodic verification sampling and analysis meet appropriate data quality standards to address this issue.

We, therefore, conclude that Sandvik's wastewater treatment sludge is not a substantial or potential hazard to human health and the environment when disposed of in a Subtitle D landfill. Further, the data presented by Sandvik in their petition supports the EPA's conclusion that the petitioned waste does not exhibit any hazardous characteristic, and that there are no other factors that would warrant retaining the waste as hazardous. On this basis, we propose to grant the Sandvik's petition to delist this waste. If this exclusion is finalized, and subject to the conditions of the final delisting, Sandvik must dispose of this waste in a Subtitle D landfill permitted or licensed by a state and will remain obligated to verify that the waste continues to meet the allowable concentrations set forth here. Sandvik must also continue to demonstrate that the waste does not exhibit any hazardous characteristics pursuant to 40 CFR part 261 Subpart C.

IV. Conditions for Exclusion

A. When would the EPA finalize the proposed delisting exclusion?

HSWA specifically requires the EPA to provide notice and an opportunity for comment before granting or denying a final exclusion. Thus, EPA will not make a final decision or grant an exclusion until it has addressed all timely public comments on today's proposal, including any at public hearings.

Since this rule would reduce the existing requirements for persons generating hazardous wastes, the regulated community does not need a six-month period to come into compliance in accordance with § 3010 of RCRA as amended by HSWA.

B. How will Sandvik manage the waste if it is delisted?

If the petitioned waste is delisted, Sandvik must dispose of it in a Subtitle D landfill which is permitted, licensed, or registered by a state to manage industrial waste.

C. What are the maximum allowable concentrations of hazardous constituents in the waste?

Concentrations measured in the waste of the following constituents must not exceed the concentrations in Table 3 below. The EPA notes that for barium, chromium, and silver, the DRAS model output predicts a maximum concentration in an extract of the waste that exceeds the toxicity characteristic regulatory designation level (TC Limit) for that constituent. Since wastes that are a candidate for delisting cannot exhibit a characteristic, the fourth column in Table 3 caps the maximum TCLP concentration of the waste at the toxicity characteristic regulatory level for barium, chromium and silver. These capped levels for the maximum TCLP concentration are the enforceable decision criteria for demonstrating that the waste meets delisting criteria.

TABLE 3—VERIFICATION CONSTITUENTS AND COMPLIANCE CONCENTRATIONS

Constituent	Total concentration DRAS model (mg/kg)	TCLP concentration DRAS model (mg/l)	TCLP concentration DRAS model capped at TC limit (mg/l)
Arsenic	9,840	0.042	0.042
Barium	N/A	176	100
Cadmium	37,100	0.451	0.451
Chromium	77,500	9.54	5.00
Cobalt	103,000	1.06	1.06
Copper	N/A	120	120
Fluoride	N/A	194	194
Lead	N/A	2.95	2.95
Nickel	N/A	66.4	66.4
Silver	N/A	38.8	5.00
Vanadium	N/A	16.9	16.9
Zinc	N/A	992	992

The EPA notes that in multiple instances the maximum allowable total constituent concentrations provided by the DRAS model exceed 100% of the waste—these DRAS results are an artifact of the risk calculations that do not have physical meaning. In instances where DRAS predicts a maximum constituent greater than 100 percent of the waste (that is, greater than 1,000,000 mg/kg or mg/L, respectively, for total and TCLP concentrations), the EPA is not requiring Sandvik to perform sampling and analysis for that constituent and sampling type (total or TCLP). In these instances, the corresponding entry in Table 3 above is ''N/A.''

D. How frequently must Sandvik test the waste?

Sandvik must analyze a representative sample of the wastewater treatment sludges on an annual basis to demonstrate that the constituents of concern in the petitioned waste do not exceed the concentrations of concern in section IV.C above. Sandvik must use methods with sufficient analytical sensitivity and appropriate quality control procedures. SW–846 Method 1311 must be used for generation of the leachate extract used in the testing of the subject waste. SW–846 Method 1311 is incorporated by reference in 40 CFR 260.11.

A total analysis of the waste (accounting for any filterable liquids and the dilution factor inherent in the TCLP method) may be used to estimate the TCLP concentration as provided for in section 1.2 of Method 1311. The EPA is not requiring Sandvik to use Method 1330 for extraction of wastes, since Method 1330 is applicable to API separator sludges, rag oils, slop oil emulsions, and other oil wastes derived from petroleum refining, which are fundamentally different wastes than those proposed by Sandvik for delisting.

E. What data must Sandvik submit?

Sandvik must submit the data obtained through annual verification testing to U.S. EPA Region 10, Office of Air and Waste, 1200 6th Avenue, Suite 155, OAW–150, Seattle, Washington 98101 upon each anniversary of the effective date of this exclusion. Sandvik must submit sampling data from both titanium and zirconium manufacturing processes provided both of these materials have been in production and contributed to candidate wastes within the three (3) month period prior to each anniversary of the effective date of this delisting. If both materials are not in production with the specified three-month period, then only data from that material in production need be submitted.

Sandvik must compile, summarize, and maintain on-site for a minimum of five years, records of analytical data required by this rule, and operating conditions relevant to those data analytical data. Sandvik must make those records available for inspection. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12).

F. What happens if Sandvik fails to meet the conditions of the exclusion?

If Sandvik violates the terms and conditions established in the exclusion, the Agency may start procedures to withdraw the exclusion.

If the verification testing of the waste does not demonstrate compliance with the delisting concentrations described in section IV.C above, or other data (including but not limited to leachate data or groundwater monitoring data from the final land disposal facility) relevant to the delisted waste indicates that any constituent is at a concentration in waste above specified delisting verification concentrations in Table 3, Sandvik must notify the Agency within 10 days of first possessing or being made aware of the data. The exclusion will be suspended and the waste managed as hazardous until Sandvik has received written approval from the EPA to continue the exclusion. Sandvik may provide sampling results which support the continuation of the delisting exclusion.

The EPA has the authority under RCRA and the Administrative Procedures Act, 5 U.S.C. 551 (1978*) et seq.* to reopen a delisting decision if we receive new information indicating that the conditions of this exclusion have been violated, or are otherwise not being met.

G. What must Sandvik do if the process changes?

If Sandvik significantly changes the manufacturing or treatment process or the chemicals used in the manufacturing or treatment process, Sandvik may not handle the wastewater treatment sludge generated from the new process under this exclusion until it has demonstrated to the EPA that the waste meets the concentrations set forth in section IV.C and that no new hazardous constituents listed in Appendix VIII of 40 CFR part 261 have been introduced. Sandvik must manage wastes generated after the process change as hazardous waste until Sandvik has received written notice from the EPA that the demonstration has been accepted.

V. How would this action affect the states?

Because the EPA is proposing to issue this exclusion under the federal RCRA delisting regulations, only states subject to federal RCRA delisting provisions will be affected. This exclusion may not be effective in states which have received authorization from the EPA to make their own delisting decisions.

The EPA allows states to impose their own non-RCRA regulatory requirements that are more stringent than the EPA's, under § 3009 of RCRA. These more stringent requirements may include a provision that prohibits a federally issued exclusion from taking effect in the state. 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 to administer a delisting program in place of the federal program, that is, to make state delisting decisions. Therefore, this exclusion does not apply in those authorized states. If Sandvik manages the waste in any state with delisting authorization, Sandvik must obtain delisting authorization or other determination from the receiving state before it can manage the waste as nonhazardous in that state.

While Washington State has received final authorization to implement most of its dangerous waste program regulations in lieu of the federal program, including the listing and identification of F006 wastes (See 51 FR 3782 (January 30, 1986), it has not been authorized to implement its delisting regulations program in lieu of the federal program. The EPA notes that Washington State has provisions in the Washington Administrative Code (WAC) 173–303–910(3) similar to the federal provisions upon which this delisting is based. These provisions are in effect as a matter of state law. Thus, Sandvik must seek approval from Washington State at the state level in addition to this proposed delisting.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed action is exempt from review by the Office of Management and Budget because it is a rule of particular applicability, not general applicability.

The proposed action approves a delisting petition under RCRA for the petitioned waste at a particular facility.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This proposed action is not an Executive Order 13771 regulatory action because actions such as approval of delisting petitions under RCRA are exempted under Executive Order 12866.

C. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) because it only applies to a particular facility.

D. Regulatory Flexibility Act

E. Because this rule is of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provision of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

F. Unfunded Mandates Reform Act

This proposed action does not contain any unfunded mandate as described in the Unfunded Mandates Reform Act (2 U.S.C. 1531–1538) and does not significantly or uniquely affect small governments. The action imposes no new enforceable duty on any state, local, or tribal governments or the private sector.

G. Executive Order 13132: Federalism

This proposed action does not have federalism implications. It 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.

H. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed action does not have tribal implications as specified in Executive Order 13175. This proposed action applies only to a particular facility on non-tribal land. Thus, Executive Order 13175 does not apply to this action.

I. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This proposed action's health and risk assessments using the Agency's Delisting Risk Assessment Software (DRAS), which considers health and safety risks to children, are described in section III.E above. The technical support document and the user's guide for DRAS are included in the docket.

J. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This proposed action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

K. National Technology Transfer and Advancement Act

This proposed action does not involve technical standards as described by the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note).

L. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this proposed action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples. The EPA has determined that this proposed action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The Agency's risk assessment, as described in section III.E above, did not identify risks from management of this material in an authorized, solid waste landfill (*e.g.* RCRA Subtitle D landfill, commercial/industrial solid waste landfill, etc.). Therefore, the EPA believes that any populations in proximity of the landfills used by this facility should not be adversely affected by common waste management practices for this delisted waste.

M. Congressional Review Act

This proposed action is exempt from the Congressional Review Act (5 U.S.C. 801 *et seq.*) because it is a rule of particular applicability.

List of Subjects in 40 CFR Part 261

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

Dated: August 21, 2018.

Jan Hastings,

Deputy Director, Office of Air and Waste.

For the reasons set out in the preamble, the EPA proposes to amend 40 CFR part 261 as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

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

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

■ 2. Amend Table 1 of Appendix IX to Part 261 by adding the following waste stream entry ''Sandvik Special Metals'' in alphabetical order to read as follows:

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

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * * * * *
Sandvik Special Metals.	Kennewick, Washington.	Wastewater treatment sludges, F006, generated at Sandvik Special Metals (Sandvik) facility in Kennewick, Washington at a maximum annual rate of 1,500 cubic yards per year. The sludge must be disposed of in a Subtitle D landfill which is licensed, permitted, or otherwise authorized by a state to accept the delisted wastewater treatment sludge. The exclusion becomes effective as of [the date of final publication]. 1. *Delisting Levels:* (A) The constituent concentrations in a representative sample of the waste must not exceed the following levels: Total concentrations (mg/kg): Arsenic—9,840; Cadmium—37,100; Chromium—77,500; Cobalt—103,000. TCLP Concentrations (mg/l in the waste extract): Arsenic—0.042; Barium—100; Cadmium—0.451; Chromium—5.00; Cobalt—1.06; Copper—120; Fluoride—194; Lead—2.95; Nickel—66.4; Silver—5.00; Vanadium—16.9; Zinc—992.

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

Facility	Address	Waste description
		2. *Annual Verification Testing:* To verify that the waste does not exceed the delisting concentrations specified in Section 1.A, Sandvik must collect and analyze one representative waste sample with coolant on an annual basis no later than each anniversary of the effective date of this delisting using methods with appropriate detection concentrations and elements of quality control. If both titanium and zirconium products have been in production and contributed to candidate wastes within the three-month period prior to each anniversary of the effective date of this delisting, samples of waste from both manufacturing processes must be collected for that reporting cycle. Otherwise, sampling only of that material in production within the specified three-month period is required. Sampling data must be provided to the EPA no later 60 days following each anniversary of the effective date of this delisting, or such later date as the EPA may agree to in writing. Sandvik must conduct all verification sampling according to a written sampling plan and associated quality assurance project plan that ensures analytical data are suitable for their intended use, which must be made available to the EPA upon request. Sandvik's annual submission must also include a certification that all wastes satisfying the delisting concentrations in Condition 1.A have been disposed of in a Subtitle D landfill which is licensed, permitted, or otherwise authorized by a state to accept the delisted wastewater treatment sludge. 3. *Changes in Operating Conditions:* Sandvik must notify the EPA in writing if it significantly changes the manufacturing process, the chemicals used in the manufacturing process, the treatment process, or the chemicals used in the treatment process. Sandvik must handle wastes generated after the process change as hazardous until it has demonstrated that the wastes continue to meet the delisting concentrations in section 1.C, demonstrated that no new hazardous constituents listed in 40 CFR part 261 Appendix VIII have been introduced into the manufacturing process or waste treatment process, and it has received written approval from the EPA that it may continue to manage the waste as non-hazardous. 4. *Data Submittals:* Sandvik must submit the data obtained through verification testing or as required by other conditions of this rule to the Director, Office of Air and Waste, U.S. EPA Region 10, 1200 6th Avenue Suite 155, OAW–150, Seattle, Washington, 98070 or his or her equivalent. The annual verification data and certification of proper disposal must be submitted within 60 days after each anniversary of the effective date of this delisting exclusion, or such later date as the EPA may agree to in writing. Sandvik must compile, summarize, and maintain on-site for a minimum of five years, records of analytical data required by this rule, and operating conditions relevant to those data. Sandvik must make these records available for inspection. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12). If Sandvik fails to submit the required data within the specified time or maintain the required records on-site for the specified time, the EPA may, at its discretion, consider such failure a sufficient basis to reopen the exclusion as described in paragraph 5. 5. *Reopener Language*—(A) If, any time after disposal of the delisted waste, Sandvik possesses or is otherwise made aware of any data relevant to the delisted waste indicating that any constituent is at a higher than the specified delisting concentration, then Sandvik must report such data, in writing, to the Director, Office of Air and Waste, EPA, Region 10, or his or her equivalent, within 10 days of first possessing or being made aware of that data. (B) Based on the information described in paragraph (A) and any other information received from any source, the EPA will make a preliminary determination as to whether the reported information requires Agency action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (C) If the EPA determines that the reported information does require Agency action, the EPA will notify Sandvik in writing of the actions it believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing Sandvik with an opportunity to present information as to why the proposed Agency action is not necessary or to suggest an alternative action. Sandvik shall have 30 days from the date of the EPA's notice to present the information. (D) If after 30 days Sandvik presents no further information or after a review of any submitted information, the EPA 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 EPA's determination shall become effective immediately, unless the EPA provides otherwise.
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