

(C) The exemption line is then defined by the equation, $N/V = C(0.84 D/W)^{-0.9}$ where the constant, C, is the same as that found in paragraph (g)(2)(i)(B) of this section.

(D) The exempted range includes all values of N/V and D/W which simultaneously fall to the lower left of the exemption line as drawn on the graph.

(ii) Its design parameters fall within the alternate exempted range for that manufacturer that year. The alternate exempted range is determined by substituting rated horsepower (hp) for displacement (D) in the exemption procedure described in paragraph (g)(2)(i) of this section and by using the product line $N/V = C(hp/W)^{-0.9}$.

(A) Rated horsepower shall be determined by using the Society of Automotive Engineers Test Procedure J 1349, or any subsequent version of that test procedure. Any of the horsepower determinants within that test procedure may be used, as long as it is used consistently throughout the manufacturer's product line in any model year.

(B) No exemptions will be allowed under paragraph (g)(2)(ii) of this section to any manufacturer that has exempted vehicle configurations as set forth in paragraph (g)(2)(i) of this section.

(iii) Its acceleration time (the time it takes a vehicle to accelerate from 0 to a speed not less than 40 miles per hour and not greater than 50 miles per hour) under high-altitude conditions is greater than the largest acceleration time under low-altitude conditions for that manufacturer for that year. The procedure to be followed in making this determination is:

(A) The manufacturer shall list the vehicle configuration and acceleration time under low-altitude conditions of that vehicle configuration which has the highest acceleration time under low-altitude conditions of all the vehicle configurations it will offer for the model year in question. The manufacturer shall also submit a description of the methodology used to make this determination.

(B) The manufacturer shall then list the vehicle configurations and acceleration times under high-altitude conditions of all those vehicles configurations which have higher acceleration times under high-altitude conditions than the highest acceleration time at low altitude identified in paragraph (g)(2)(iii)(A) of this section.

(iv) In lieu of performing the test procedure of paragraph (g)(2)(iii) of this section, its acceleration time can be estimated based on the manufacturer's engineering evaluation, in accordance

with good engineering practice, to meet the exemption criteria of paragraph (g)(2)(iii) of this section.

(3) The sale of a vehicle for principal use at a designated high-altitude location that has been exempted as set forth in paragraph (g)(2) of this section will be considered a violation of section 203(a)(1) of the Clean Air Act.

Subpart L—[Amended]

6. Section 86.1105–87 of Subpart L is amended by removing and reserving paragraph (a), redesignating paragraph (c) as paragraph (d), and adding a new paragraph (c), to read as follows:

§ 86.1105–87 Emission standards for which nonconformance penalties are available.

(a) [Reserved]

(c) Effective in the 1991 model year, NCPs will be available for the following emission standards: (1) Diesel light-duty truck (rated in excess of 6,000 pounds GVWR) particulate emission standard of 0.13 grams per vehicle mile.

[FR Doc. 88–24963 Filed 10–28–88; 8:45 am]
BILLING CODE 6560–50–M

40 CFR Parts 261 and 302

[FRL–3469–7]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Removal of Iron Dextran from the List of Hazardous Wastes

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) today is amending its regulations under the Resource Conservation and Recovery Act (RCRA) to remove iron dextran (ferric dextran) (CAS No. 9004–66–4) from § 261.33, the list of commercial chemical products which are hazardous wastes when discarded or intended to be discarded; and to remove iron dextran from Appendix VIII of Part 261, the list of RCRA hazardous constituents. EPA also is removing iron dextran from the list of hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA is taking this action because iron dextran, when improperly treated, stored, transported, disposed of, or otherwise managed, is not capable of posing a substantial present or potential

hazard to human health or the environment.

DATE: This regulation becomes effective on October 31, 1988.

ADDRESSES: The Office of Solid Waste (OSW) docket is located in the sub-basement at 401 M Street, SW., Washington, DC 20460, and is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. The public must make an appointment to review docket materials by calling (202) 475–9327. Refer to "Docket number F–85–IDEP–FFFFF" when making appointments to review any background documents for this rulemaking. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost; additional copies cost \$0.20 per page.

FOR FURTHER INFORMATION CONTACT: The RCRA/Superfund Hotline at (800) 424–9346 or at (202) 382–3000. For technical information contact Denny Cruz, Office of Solid Waste (SW–332), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 382–4802.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1985, EPA proposed to amend its regulations under RCRA to remove iron dextran from 40 CFR 261.33, the list of commercial chemical products which are hazardous wastes when discarded or intended to be discarded; and to remove iron dextran from Appendix VIII of Part 261, the list of RCRA hazardous constituents (50 FR 46468). EPA also proposed to remove iron dextran from the CERCLA list of hazardous substances. This proposal responded to an August 9, 1983, petition submitted by Fisons Corporation pursuant to § 260.20 to delist iron dextran.

The Agency originally listed iron dextran in 40 CFR 261.33(f) (EPA Hazardous Waste No. U139) and Appendix VIII based upon the listing criteria in 40 CFR 261.11(a)(3)(i)–(xi) and the Agency's Carcinogen Assessment Group (CAG) assessment that iron dextran exhibited sufficient evidence of carcinogenicity. Iron dextran has been designated as a Class B2 carcinogen by CAG according to EPA's Guidelines for Carcinogen Risk Assessment (51 FR 33992) based upon sufficient evidence of carcinogenicity in animals, but inadequate data in humans. A further review of the evidence for the carcinogenicity dextran reveals that it is limited to studies in which iron dextran was given to experimental animals by subcutaneous or intramuscular injection;

in addition, there is no evidence that iron dextran is carcinogenic when orally or otherwise administered. Furthermore, the large size of the iron dextran complex (molecular weight approximately 180,000)¹ prevents its absorption by the oral, dermal, or inhalation routes. In fact, dextran, to which the iron is complexed, is a large polysaccharide (molecular weight 40,000—75,000) that is commonly used parenterally (nonintestinally) as a plasma expander. By definition, plasma expanders have an osmotic pressure comparable to plasma, preventing them from crossing membrane barriers, and thereby effectively prohibiting their absorption from the circulatory system.² Since they cannot cross membrane barriers, they cannot be absorbed by the oral, dermal, or inhalation routes. Iron dextran is much larger than dextran; thus, it too will not be absorbed. Therefore, EPA now concludes that iron dextran, when discarded, does not pose a significant hazard to human health or the environment because iron dextran, due to its size, stability, and osmotic pressure, is not absorbed by the oral, dermal, or inhalation routes, and exposure via subcutaneous or intramuscular injection at levels of concern is not a likely mismanagement scenario. Accordingly, iron dextran also does not meet the standard for listing a hazardous constituent on Appendix VIII of Part 261 set forth at § 261.11(a). That section provides for listing in Appendix VIII only if a constituent has been shown in scientific studies to have toxic, carcinogenic, mutagenic, or teratogenic effects on human or other life forms. Applying this standard in the context of Subtitle C, that is, to protect human health and the environment from the risks of improper hazardous waste management, EPA concludes that the available scientific studies, which address carcinogenic effects of subcutaneous injection of iron dextran, when viewed in light of the lack of absorption of iron dextran via oral, dermal, and inhalation routes, do not demonstrate carcinogenic effects as a result of a plausible mismanagement scenario. Similarly, iron dextran also does not meet the standard for listing of a hazardous waste set forth at § 261.11(a)(3). Again, because iron dextran cannot be absorbed by the oral, dermal, or inhalation routes, it is not "capable of posing a substantial present or potential hazard to human health or

the environment when improperly treated, stored, transported, disposed of, or otherwise managed."

II. Response to Comments

EPA received comments from the Natural Resources Defense Council (NRDC) in response to the proposed rulemaking. The NRDC presented the following arguments: (1) Sufficient evidence exists of carcinogenicity in experimental animals by the injection route indicating the potential to cause tumors by other routes of exposure including ingestion, (2) suggestive evidence exists in rodents that iron dextran can induce tumors at distal sites, and (3) there are case reports in the literature of injection site tumors in humans. These arguments are discussed below in more detail.

1. The commenter states that "the sufficient evidence of carcinogenicity in experimental animals by the injection route indicates the potential to cause tumors by other routes of exposure, including ingestion." The commenter states that iron dextran has not been adequately tested by other routes of administration and that in the absence of such data, "a prudent approach is to assume that iron dextran is potentially carcinogenic in humans by the oral or inhalation routes." In support of this, the commenter cites an analysis of the literature that found that of 102 chemicals reviewed, only 8.7% that were positive for carcinogenicity by a subcutaneous route were negative when tested by other routes.

The Agency agrees that other routes are potential pathways for carcinogenicity if one route has shown to be carcinogenic. However, iron dextran, because of its size, stability and osmotic pressure is unlikely to be absorbed by any route of exposure other than subcutaneous or intramuscular injection. Accordingly, it could not pose a significant hazard to human health or the environment through these other routes of exposure.

2. The commenter states "there is, in fact, some suggestive evidence in rodents that iron dextran can induce tumors at distal sites." The commenter cites, in support of this contention, one subcutaneous injection study in rats where distal tumors were elevated by 6.3% over a control incidence of 7.8% in one of four treatment groups.

The Agency has reviewed these data and does not deem this positive evidence. The increased incidence was not dose-related, it was only seen in one group, and was not statistically significant. We concluded, therefore, that the incidence of distal tumors found

in this study does not provide positive evidence of carcinogenicity.

3. The commenter cites another study in mice that discussed the possibility that iron dextran may act as a co-carcinogenic factor in the case of lymphoreticular neoplasms, increasing host susceptibility to the oncogenic virus possibly present in both test and control animals.

The Agency does not believe that this study provides conclusive evidence of carcinogenic effects; rather the Agency regards such evidence as speculation. Therefore, this suggestive result is not a significant toxic effect.

4. The commenter claims "further evidence of iron dextran's carcinogenicity is provided by very recent experiments in which iron dextran was injected in mice implanted with L1210 cell line inoculates. In these experiments, the L1210 cell line acted as a potential tumor analogue. Iron dextran not only accelerated proliferation of the L1210 cells, but also significantly increased the lethality of these cells. This provided further evidence that iron overload is carcinogenic not only at the site of entry but systemically as well."

The Agency agrees that iron overload is correlated with carcinogenicity. The studies cited by the commenter presented evidence of a high incidence of lung cancer in hematite (iron ore) miners, hepatomas in gold miners due to the excessive oral ingestion of iron-contaminated beer, and gastric cancer in people with occupations exposed to iron dust, all associated with hemochromatosis, a disorder of iron metabolism. However, the EPA does not believe that the above-cited studies provide evidence of iron dextran-induced iron overload because iron dextran cannot be absorbed by any route other than subcutaneous, nor is there evidence that subcutaneous exposure will result in concentrations of iron dextran high enough to induce iron overload-associated cancer at distal sites.

5. The commenter states "there have been a number of case reports in the literature of tumors at the injection site in humans." Specifically, the commenter cites eight cases of sarcomas that have followed intramuscular injection of iron compounds.

The Agency believes that these studies are of questionable value. All of the studies involved tumors or lesions at the site of injection. The Agency promulgated a policy on September 24, 1986, on how to deal with tumors at the site of injection in the *Guidelines for Carcinogen Risk Assessment* (51 FR 33992). These guidelines state that

¹ Lundin, P.M. 1961. The carcinogenic action of complex iron preparations. *Brit. J. Cancer* 15:838.

² Goodman, L.S. and A. Gilman, eds. 1975. *The Pharmacological Basis of Therapeutics*, 5th ed. MacMillan Publishing Co., Inc. New York, NY.

tumors at the site of injection alone are "limited" evidence of the carcinogenicity of a compound. Furthermore, three of the studies involved the injection of Jectofer, an iron sorbitol and citric acid complex, rather than iron dextran, and therefore any conclusion drawn from these studies about the carcinogenicity of iron dextran is questionable.

In summary, the Agency is issuing a final rule to remove iron dextran from the list of hazardous wastes on the grounds that, because of its size, it does not present a carcinogenic risk to humans by any route of exposure other than possible subcutaneous. Exposure via subcutaneous or intramuscular exposure at levels of concern, however, is not a plausible mismanagement scenario. Multiple doses of milliliter quantities of iron dextran need to be injected into the system to possibly cause a detrimental effect. This is a highly unlikely mismanagement scenario. There are no other known reasons to list iron dextran.

Iron dextran is not absorbed by oral, dermal, or inhalation routes. It is a drug that is regulated by the Food and Drug Administration for non-intestinal use only. All of the animal and human data cited by the commenter as supportive evidence of systemic carcinogenicity have been reviewed by the Agency, and are regarded as being inadequate, inconclusive, or speculative.

III. Relationship to Other Regulatory Authorities

Whenever a hazardous waste or waste stream is listed under section 3001 of RCRA, it is co-listed as a hazardous substance under the statutory provisions of section 101(14) of CERCLA. The Agency, in its April 4, 1985, final rule on notification requirements and reportable quantity (RQ) adjustments, noted that iron dextran, along with numerous other elements, compounds, mixtures, solutions, and hazardous wastes, was designated as a hazardous substance under section 102(a) of CERCLA. (See 50 FR 13456.)

In addition to amending the RCRA regulations to remove iron dextran from 40 CFR 261.33(f) and 40 CFR Part 261, Appendix VIII, the Agency is today removing iron dextran from the CERCLA section 102(a) list of hazardous substances. As a result of the removal of iron dextran from the § 261.33(f) and Part 261 Appendix VIII lists, the Agency has no basis upon which to retain iron dextran on the CERCLA section 102(a) list of hazardous substances. The Agency's designation of iron dextran under section 102(a) was based solely

upon its inclusion as a hazardous substance under section 101(14) of CERCLA. The Agency has previously stated that when hazardous substances are added to or removed from the lists which comprise the CERCLA section 101(14) list of hazardous substances, corresponding changes will be made simultaneously both to the list of hazardous substances in section 101(14) and the list of CERCLA hazardous substances designated under section 102(a) and published in 40 CFR Table 302.4. (See 48 FR 23552, 23554 (May 25, 1983 proposed rule); Technical Background Document to Support Rulemaking Pursuant to CERCLA Section 102 (Volume 1, March 1985) at ES-4.)

Although iron dextran is today being removed from the CERCLA § 102(a) list, wastes containing iron dextran may, in certain circumstances, be hazardous substances under section 102(a). Wastes containing iron dextran which exhibit any of the hazardous characteristics identified in 40 CFR 261.20 through 261.40, are CERCLA hazardous substances under section 101(14) and are designated as section 102(a) CERCLA hazardous substances. All unlisted hazardous substances have a reportable quantity of 100 pounds under 40 CFR 302.5(b).

IV. State Authority

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) Following authorization, EPA retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in the State which the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obliged to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by the HSWA take effect in authorized States at the same time that they take effect in non-authorized States. EPA is directed to implement those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA applies in authorized States in the interim.

B. Effect on State Authorizations

Today's rule promulgates regulations that are not effective in authorized States since the regulations are not being imposed pursuant to the Hazardous and Solid Waste Amendments of 1984. Thus, the regulations will be applicable only in those States that do not have interim or final authorization. In authorized States, the regulations will not be applicable until the State revises its program to adopt equivalent regulations under State law.

40 CFR 271.21(e)(2) requires that States that have final authorization must modify their programs to include equivalent regulations within a year of promulgation of these regulations if only regulatory changes are necessary, or within two years of promulgation if statutory changes are necessary. These deadlines can be extended in exceptional cases (40 CFR 271.21(e)(3)). Once EPA approves the modification, the State requirements become Subtitle C RCRA requirements.

It should be noted that authorized States are only required to modify their programs when EPA promulgates Federal regulations that are more stringent or broader in scope than the existing Federal regulations. For those Federal program changes that are less stringent or reduce the scope of the Federal program, States are not required to modify their programs. This is a result of section 3009 of RCRA, which allows States to impose regulations in addition to those in the Federal program. The regulations promulgated today at §§ 261.33(f) and 302.4 are considered to reduce the scope of the existing Federal regulations. Therefore, authorized States are not required to modify their programs to adopt regulations equivalent or substantially equivalent to the provisions listed above.

V. Effective Date

This rule is effective immediately. The Hazardous and Solid Waste

Amendments of 1984 amended section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six month period to come into compliance. This is the case here since this rule reduces, rather than increases, the existing requirements for persons generating hazardous wastes. In light of the unnecessary hardship and expense which would be imposed on the petitioner by an effective date six months after promulgation and the fact that such a deadline is not necessary to achieve the purpose of section 3010, this rule is effective immediately.

VI. Regulatory Impact

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This rule reduces the regulatory requirements applicable to the regulated community. It is not major because it would not result in an effect on the economy of \$100 million or more, nor would it result in a major increase in costs or prices to individual industries, consumers, Federal, State or local government agencies, or geographic regions. Finally, there would be no adverse impact on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, this amendment is not a major regulation, and no Regulatory Impact Analysis has been conducted.

This amendment was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

VII. Regulatory Flexibility Act

Pursuant to 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 (*i.e.*, small business, small organizations, and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant economic impact on a substantial number of small entities.

This amendment will not have a significant economic impact on small entities since it reduces regulatory requirements. Moreover, relatively few small entities dispose of iron dextran. Accordingly, I certify that this final rule will not have a significant economic impact on a substantial number of small

entities. This regulation, therefore, does not require a regulatory flexibility analysis.

VIII. Paperwork Reduction Act

This final rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

List of Subjects

40 CFR Part 261

Hazardous wastes, Recycling.

40 CFR Part 302

Air pollution control, Chemicals, Hazardous materials, Hazardous substance, Hazardous wastes, Intergovernmental relations, Natural resources, Nuclear materials, Pesticides and pests, Radioactive materials, Recycling, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control.

Date: October 21, 1988.

John A. Moore,
Acting Administrator.

For the reasons set out in the preamble, Title 40 of the Code of Federal Regulations 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: Sections 1006, 2002(a), 3001, and 3002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6921 and 6922).

§ 261.33 [Amended]

2. Amend the table in § 261.33(f) by removing the listing: "U139 . . . 900466-4 . . . Iron dextran."

Appendix VIII [Amended]

3. Amend Appendix VIII by removing the listing: "Iron dextran . . . Same . . . 9004-66-4."

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

1. The authority citation for Part 302 continues to read as follows:

Authority: Section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9602, Sections 311 and 501(a) of the Federal Water Pollution Control Act, 33 U.S.C. 1321 and 1361.

§ 302.4 [Amended]

2. Amend § 302.4 by removing the entire entry for "iron dextran" and "ferric dextran" from Table 302.4 and its Appendix A.

[FR Doc. 88-25078 Filed 10-28-88; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 261 and 302

[FRL-3469-6]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Removal of Strontium Sulfide From the List of Hazardous Wastes

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) today is amending its regulations under the Resource Conservation and Recovery Act (RCRA) to remove strontium sulfide (CAS No. 1314-96-1) from § 261.33, the list of commercial chemical products which are hazardous wastes when discarded or intended to be discarded; and to remove strontium sulfide from Appendix VIII of Part 261, the list of RCRA hazardous constituents. EPA also is removing strontium sulfide from the list of hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA is taking this action because strontium sulfide, when improperly treated, stored, transported, disposed of, or otherwise managed, does not pose a significant hazard to human health or the environment.

DATE: This regulation becomes effective on October 31, 1988.

ADDRESSES: The Office of Solid Waste (OSW) docket is located in the sub-basement at 401 M Street, SW., Washington, DC 20460, and is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. The public must make an appointment to review docket materials by calling (202) 475-9327. Refer to "Docket number F-83-SSPA-FFFFF" when making appointments to review any background documents to this rulemaking. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost; additional copies cost \$0.20 per page.

FOR FURTHER INFORMATION CONTACT: The RCRA/Superfund Hotline at (800) 424-9346 or at (202) 382-3000. For technical information contact Denny Cruz, Office of Solid Waste (SW-332),

U.S. Environmental Protection Agency,
401 M Street, SW., Washington, DC
20460, (202) 382-4802.

SUPPLEMENTARY INFORMATION:

I. Authority

These regulations are being promulgated under the authority of sections 2002(a) and 3001 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a) and 6921 (commonly referred to as RCRA), and section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9602.

II. Background

On August 26, 1983, EPA proposed to amend its regulations under RCRA to remove strontium sulfide from 40 CFR 261.33, the list of commercial chemical products which are hazardous wastes when discarded or intended to be discarded; and to remove strontium sulfide from Appendix VIII of Part 261, the list of RCRA hazardous constituents (48 FR 39000). This proposal was in response to a February 5, 1981 petition submitted by Chemical Products Corporation, pursuant to § 280.20 to delist strontium sulfide.

The Agency originally listed strontium sulfide in 40 CFR 261.33(e) (EPA Hazardous Waste No. P107) and Appendix VIII based upon the listing criteria in 40 CFR 261.11(a)(2) and its oral (human) lowest lethal dose (LDL₅₀) of 50 mg/kg as listed in the *Registry of Toxic Effects of Chemical Substances (RTECS)* (National Institute for Occupational Safety and Health (NIOSH), 1978). A further look at the evidence for the toxicity of strontium sulfide reveals that the oral (human) LDL₅₀ value of 50 mg/kg was actually reported in the original source, *The Clinical Toxicology of Commercial Products* (Gosselin et al., 1976), as a range of 50 to 500 mg/kg for "Probable Oral Lethal Dose (Human)." The lowest value of this range (50 mg/kg) was subsequently reported by NIOSH in spite of a footnote in the original source which states that the toxicity for strontium sulfide was based upon "obviously inadequate data" and that it could "represent no more than guesses."

The more recent *RTECS* supplement (NIOSH, 1985) does not list the oral (human) LDL₅₀ value for strontium sulfide because of the lack of reliable data on its toxicity.

The Agency has searched for current reliable data on the acute and chronic (specifically, teratogenic) toxicity of strontium sulfide in numerous toxicological sources through the Office of Research and Development and has found no additional data. In view of this

lack of reliable information, the Agency believes that there is insufficient evidence to support the continued listing of strontium sulfide as either an acute hazardous waste or as a toxic waste.

It is important to note, however, that this action does not completely release wastes containing strontium sulfide from regulatory control under RCRA. The Agency believes that wastes containing high concentrations of strontium sulfide may exhibit the characteristic of reactivity (40 CFR 261.23(a)(5)) (i.e., a sulfide-bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases (e.g., H₂S), vapors, or fumes in a quantity sufficient to present a danger to human health or the environment). If the wastes exhibit the characteristic of reactivity, they must be handled as hazardous wastes.

III. Response to Comment

EPA received one comment which agreed with the Agency's proposal to delist strontium sulfide based on the most current data available.

The Agency therefore stands by its proposal to delist strontium sulfide on the basis that there is insufficient evidence to support its listing as either an acute hazardous waste or as a toxic waste.

IV. Relationship to Other Regulatory Authorities

Whenever a hazardous waste or waste stream is listed under section 3001 of RCRA, it is co-listed as a hazardous substance under the statutory provisions of section 101(14) of CERCLA. The Agency, in its April 4, 1985, final rule on notification requirements and reportable quantity (RQ) adjustments, noted that strontium sulfide, along with numerous other elements, compounds, mixtures, solutions, and hazardous wastes, was designated as a hazardous substance under section 102(a) of CERCLA. (See 50 FR 13456.)

In addition to amending the RCRA regulations to remove strontium sulfide from 40 CFR 261.33(e) and 40 CFR Part 261, Appendix VIII, the Agency is today removing strontium sulfide from the CERCLA section 102(a) list of hazardous substances. As a result of the removal of strontium sulfide from the § 261.33(e) and Part 261 Appendix VIII lists, the Agency has no basis upon which to retain strontium sulfide on the CERCLA section 102(a) list of hazardous substances. The Agency's designation of strontium sulfide under Section 102(a) was based solely upon its inclusion as a hazardous substance under section 101(14) of CERCLA. The Agency has

previously stated that when hazardous substances are added to or removed from the lists which comprise the CERCLA section 101(14) list of hazardous substances, corresponding changes will be made simultaneously both to the list of hazardous substances in section 101(14) and the list of CERCLA hazardous substances designated under section 102(a) and published in 40 CFR Table 302.4. (See 48 FR 23552, 23554 (May 25, 1983 proposed rule); Technical Background Document to Support Rulemaking Pursuant to CERCLA section 102. (Volume 1, March 1985) at ES-4.)

Although strontium sulfide is today being removed from the CERCLA section 102(a) list, wastes containing high concentrations of strontium sulfide may, in certain circumstances, be hazardous substances under section 102(a). As discussed above, the Agency believes that a waste containing high concentrations of strontium sulfide may exhibit the characteristic of reactivity such that it must be handled as a hazardous waste under 40 CFR 261.23. Unlisted RCRA hazardous wastes, or hazardous wastes exhibiting any of the characteristics identified in 40 CFR 261.20 through 61.40, are CERCLA hazardous substances under § 101(14) and are designated as section 102(a) CERCLA hazardous substances. (See 40 CFR 302.4(b).) Thus, if wastes containing strontium sulfide exhibit the characteristic of reactivity under 40 CFR 261.23, these wastes would also be CERCLA hazardous substances under section 102(a). All unlisted hazardous substances have a reportable quantity of 100 pounds under 40 CFR 302.5(b).

V. State Authority

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) Following authorization, EPA retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA would not issue permits for

any facilities in the State that the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obliged to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by the HSWA take effect in authorized States at the same time that they take effect in non-authorized States. EPA is directed to implement those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA applies in authorized States in the interim.

B. Effect on State Authorizations

Today's rule promulgates regulations that are not effective in authorized States because the regulations are not being imposed pursuant to the Hazardous and Solid Waste Amendments of 1984. Thus, the regulations will be applicable only in those States that do not have interim or final authorization. In authorized States, the regulations will not be applicable until the State revises its program to adopt equivalent regulations under State law.

40 CFR 271.21(e)(2) requires that States that have final authorization must modify their programs to include equivalent regulations within a year of promulgation of these regulations if only regulatory changes are necessary, or within two years of promulgation if statutory changes are necessary. These deadlines can be extended in exceptional cases (40 CFR 271.21(e)(3)). Once EPA approves the modification, the State requirements become Subtitle C RCRA requirements.

It should be noted that authorized States are only required to modify their programs when EPA promulgates Federal regulations that are more stringent or broader in scope than the existing Federal regulations. For those Federal program changes that are less stringent or reduce the scope of the Federal program, States are not required to modify their programs. This is a result of section 3009 of RCRA, which allows States to impose regulations in addition to those in the Federal program. The regulations promulgated today at § 261.33(e) are considered to reduce the scope of the existing Federal

regulations. Therefore, authorized States are not required to modify their programs to adopt regulations equivalent or substantially equivalent to the provisions listed above.

VI. Effective Date

This rule is effective immediately. The Hazardous and Solid Waste Amendments of 1984 amended section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. This is the case here since this rule reduces, rather than increases, the existing requirements for persons generating hazardous wastes. In light of the unnecessary hardship and expense which would be imposed on the petitioner by an effective date six months after promulgation and the fact that such a deadline is not necessary to achieve the purpose of section 3010, this rule is effective immediately. These reasons also provide a basis for making this rule effective immediately under the Administrative Procedure Act, pursuant to 5 U.S.C. 553(d).

VII. Regulatory Impact

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This rule reduces the regulatory requirements applicable to the regulated community. It is not major because it would not result in an annual effect on the economy of \$100 million or more, nor would it result in a major increase in costs or prices to individual industries, consumers, Federal, State, or local government agencies, or geographic regions. Finally, there will be no adverse impacts on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, this amendment is not a major regulation, and no Regulatory Impact Analysis has been conducted.

This amendment was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

VIII. Regulatory Flexibility Act

Pursuant to 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 (i.e., small business, small

organizations, and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant economic impact on a substantial number of small entities.

This amendment will not have a significant economic impact on small entities since it reduces regulatory requirements. Moreover, relatively few small entities disposed of strontium sulfide. Accordingly, I certify that this final rule will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

IX. Paper Reduction Act

This final rule does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

X. References

Gosselin, R.E. et al. 1976. *The Clinical Toxicology of Commercial Products*. The Williams and Wilkins Co. Baltimore, MD.

National Institute of Occupational Safety and Health. 1978. *Registry of Toxic Effects of Chemical Substances*. USDHHS. Cincinnati, OH.

National Institute of Occupational Safety and Health. 1985. *Registry of Toxic Effects of Chemical Substances: 1983-1984 Cumulative Supplement to the 1981-1982 Edition*. USDHHS. Cincinnati, OH.

List of Subjects

40 CFR Part 261

Hazardous wastes, Recycling.

40 CFR Part 302

Air pollution control, Chemicals, Hazardous materials, Hazardous substance, Hazardous wastes, Intergovernmental relations, Natural resources, Nuclear materials, Pesticides and pests, Radioactive materials, Recycling, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control.

Date: October 21, 1988.

John A. Moore,
Acting Administrator.

For the reasons set out in the preamble, Title 40 of the Code of Federal Regulations 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, 6938.

§ 261.33 [Amended]

2. Amend the table in § 261.33(e) by removing the listing: "P107 * * * 1314-96-1 * * * Strontium sulfide."

Appendix VIII—[Amended]

3. Amend Appendix VIII by removing the listing: "Strontium sulfide * * * Same * * * 1314-96-1."

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

1. The authority citation for Part 302 continues to read as follows:

Authority: Section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1990, 42 U.S.C. 9602; Sections 311 and 501(a) of the Federal Water Pollution Control Act, 33 U.S.C. 1321 and 1361.

§ 302.4 [Amended]

2. Amend § 302.4 by removing the entry for "strontium sulfide" from Table 302.4 and its Appendix A.

[FR Doc. 88-25079 Filed 10-28-88; 8:45 am]

BILLING CODE 6550-50-M

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service****50 CFR Part 17****Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for the California Freshwater Shrimp**

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The Service determines the California freshwater shrimp (*Syncaris pacifica*) to be an endangered species. The species is threatened by introduced predatory fish and deterioration or loss of habitat resulting from water diversion, impoundments, livestock grazing, agricultural activities and development, urbanization, and water pollution. The California freshwater shrimp is known from only twelve streams in Napa, Marin, and Sonoma Counties, California. This rule implements the protection provided under the Endangered Species Act of 1973, as amended, for the California freshwater shrimp.

EFFECTIVE DATE: November 30, 1988.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Fish and Wildlife Enhancement Field Station, Division of Endangered

Species, 2800 Cottage Way, Room E-1823, Sacramento, California 95825.

FOR FURTHER INFORMATION CONTACT: Mr. Gail C. Kobetich, Field Supervisor, at the above address (916/978-4866 or FTS 460-4866).

SUPPLEMENTARY INFORMATION:**Background**

The California freshwater shrimp, *Syncaris pacifica* (Holmes), is a decapod crustacean of the family Atyidae. Samuel J. Holmes first described *S. pacifica* as *Miersia pacifica* in 1895. In 1900, Holmes erected a new genus, *Syncaris*, for the California atyids based on notable differences in the chelae (pinchers) and rostrum (horn-shaped structure between the eyes). *S. pacifica* can be distinguished from *Palaemonias*, the only other atyid genus in the United States, by its well-developed stalked eyes. *Palaemonias* are blind and dwell in caves in the eastern United States. *S. pacifica* is the only surviving species in the genus *Syncaris*.

Adults may reach 5 centimeters (cm) (2½ inches) in length. Nearly transparent in water, the adults appear out of water to be greenish-gray to almost black with pale blue uropods (tail fins). An adult female lays relatively few eggs (50-70, Hedgpeth 1975; 100-120, Eng 1981). While she carries the eggs on her body for 8 to 9 months, slow overwintering development of the eggs occurs. During this period, many larvae die due to adult female death and genetic or embryonic developmental problems. As a result, the number of embryos emerging from the eggs during May are reduced typically by 50 percent. During the first summer, larval growth is rapid, but sexual maturity is not reached until the second summer.

The California freshwater shrimp is endemic to gentle gradient (less than 1 percent), low elevation (below 115 meters (380 feet)), freshwater streams in Marin, Napa, and Sonoma Counties, California. The species, a true freshwater shrimp, inhabits quiet portions of tree-lined streams with underwater vegetation and exposed tree roots. Once common in the three counties, *S. pacifica* now occurs only within restricted portions of 12 streams. It cannot tolerate salt or brackish water and does not occur in the intertidal reaches or estuarine areas of any of the streams (Born 1968, Hedgpeth 1968, and Li 1981). The shrimp's transparency, secretive habits, and rapid escape behavior contribute to its obscurity and make it difficult to capture or detect by the casual observer. The California

Department of Fish and Game (CDFG) attributed the decline in shrimp populations primarily to degradation and loss of its habitat resulting from increased urbanization, overgrazing, agricultural development, dam construction, and water pollution (CDFG 1980). Essentially compatible with native fish species, *S. pacifica* is threatened by the introduction of exotic predators, especially fishes of the sunfish family. Because of the species' low reproductive potential, slow maturity, restricted distribution, and specialized habitat requirements, *S. pacifica* is particularly vulnerable to habitat loss and predation by exotic species against which its natural defense mechanisms are ineffective.

On June 4, 1974, the Service entered into a contract with the Sierra Club Foundation to investigate the status of freshwater shrimps in Pacific drainages. A final report under this contract was submitted in September 1975 by Dr. Joel W. Hedgpeth. Dr. Hedgpeth concluded in his report that *Syncaris pacifica* had been extirpated in some streams and was reduced in distribution and abundance in others. This report cited dredging, streambed gravel stockpiling, stream diversion, and building temporary summer gravel dams on the Austin Creek system as the major factors responsible for the decline of the California freshwater shrimp. Larry Serpa (1985) reported the species inhabited eleven streams in the Russian River, San Francisco Bay, and other coastal drainages. These streams are East Austin, Salmon, Lagunitas, Big Austin, Sonoma, Huichica, Green Valley, Jonive, Walker, Yulupa, and Blucher. This survey included a total of 52 streams in the three drainages. Bill Cox of CDFG (personal communication 1986) found shrimp in the Napa River near Calistoga. This finding increases the total number of streams in the area known to contain shrimp to 12 out of the 53 surveyed.

The California freshwater shrimp was proposed as a threatened species on January 12, 1977 in the Federal Register (42 FR 2507). That proposal was withdrawn on December 10, 1979 (44 FR 70796), under a provision of the 1978 amendments to the Endangered Species Act of 1973, which required withdrawal of all pending proposals if they were not finalized within 2 years of the proposal. On March 23, 1980, the Service received from CDFG a series of annotated maps delineating the known, current distribution of the California freshwater shrimp. These maps summarize the distribution data collected by CDFG in 1979 and 1980. Additional distributional