

§ 601.100 [Amended]**Explanation of Changes**

Procurement Manual Circular 92-1 contains several changes recently approved by the Procurement Policy Committee. A list and short description of the changes follow. The full text of the changes follows this explanation.

A. Various Parts. The simplified purchasing ceiling has been raised from \$50,000 to \$100,000. This change has also raised the competitive threshold (which is ten percent of the simplified ceiling) to \$10,000. In addition, this change has raised the thresholds for the annual procurement plan requirement and for publicizing in the Commerce Business Daily. Except for the text changes required by the new publicizing threshold, these revisions will require pen-and-ink changes throughout parts of the PM. These parts are listed on page 2 of this PM Circular.

B. Part 3.1.5.b, General Services Administration (Other Government Sources). Subsection 3.1.5.b.2 has been revised to clarify that additional competition is not required when using Federal Supply Schedules. A new subsection 3.1.5.b.3 has been added discussing the General Services Administration's Information Resource Management Service and nonmandatory schedule contracts for Federal Information Processing (FIP) Resources.

C. Part 3.2.1, Policy (Publicizing Purchasing Actions) has been revised to state that contracts which will be awarded using simplified procedures, and that solicitations which will result in contracts valued at \$100,000 and under need not be publicized.

D. Part 4.1.2, Solicitations. Subsection 4.1.2.k.4, Release of Solicitation Mailing Lists, has been revised to allow, at the contracting officer's discretion, and when adequate competition is expected, the release of a solicitation mailing list to any firm or individual who has been sent a solicitation.

Pen-and-Ink Changes

Use pen and ink to change "\$50,000" to "\$100,000" in the following PM citations:

- Part 2.1.4, Annual Procurement Summary Plans, Paragraph a.
- Part 2.3.2, Use (Specifications and Statements of Work) Paragraph c, Product Descriptions, Subparagraph 5.
- Part 3.1.5, Other Government Sources, Paragraph b, General Services Administration, Subparagraph e.2, Oral Orders.
- Part 3.1.6, Commercial Sources, Paragraph e, Determining Responsibility and Nonresponsibility.

- Part 4.2.1, Simplified Purchasing, General, Paragraph b, Ceiling.
- Part 4.2.2, Solicitations, Paragraph e, Posting and Synopsis.
- Part 11.5.2, Minor Repairs and Alterations, Paragraphs a, Applicability, and b, Purchase Method.

Text Changes**3.1.5.b.2 Federal Supply Schedules**

(a) General. Federal Supply Schedules (FSS) are summaries of ordering contracts negotiated by GSA's Federal Supply Service. They include Single-Award, Multiple-Award, and New Item Introductory Schedules. GSA (FSS) terms and conditions, rather than those used by the Postal Service, apply to orders placed against FSS. Purchasing organizations may order against FSS when they meet their quality and delivery requirements. Additional competition is not required when using FSS.

3.1.5.b.3 Information Resources Management Service (IRMS)
Nonmandatory Schedule Contracts for Federal Information Processing (FIP) Resources

Nonmandatory schedule contracts for Federal Information Processing (FIP) Resources are established by GSA's Information Resources Management Service (IRMS). FIP resources include telecommunications and FIP equipment, software, support services, maintenance, related supplies, and systems. GSA refers to these contracts as "Group 70 Schedule Contracts (ADP Equipment)" and Group 58 Schedule Contracts (Telecommunications Equipment)". GSA contract terms and conditions, rather than those used by the Postal Service, apply to orders placed against these contracts. GSA requires that needs be synopsized and that competition be obtained when these contracts are used. The procedures of 3.2.1 and 4.2.1.d satisfy the GAS requirement.

3.2.1 Policy

a. All solicitations valued at over \$100,000 must be publicized unless (1) precluded by urgency, (2) they fall within the exceptions dealing with leased space set out in Chapter 11 (3) advance notice of sources sought was previously published in the market research phase of the procurement or (4) approval has been given to simplified procedures for the procurement.

4.1.2 Solicitations

k.4 Release of Solicitation Mailing Lists. When a procurement is deemed highly competitive (i.e., five or more potential offerors) and no harm to competition is anticipated from releasing the specific source list, the contracting officer may consider it advantageous to the Postal Service to release the source list to anyone who is sent a copy of that solicitation. If the source list has not been released and is requested under the Freedom of Information Act (FOIA) it is not necessary to release it to all prospective offerors, but only to the specific FOIA requestor. The source list, in this instance, is considered general information that should not give the recipient any advantage over other offerors.

Stanley F. Mires,
Chief Counsel, Legislative Division.
[FR Doc. 92-31041 Filed 12-22-92; 8:45 am]
BILLING CODE 7710-12-M

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 61**

[AD-FRL-4548-5]

National Emission Standards for Hazardous Air Pollutants; Amendment to Vinyl Chloride Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correcting amendments.

SUMMARY: This document contains a correction to the final regulations originally published on October 21, 1976 (41 FR 46564). The regulations are found in title 40, chapter I, part 61, subpart F of the Code of Federal Regulations. They control vinyl chloride emissions resulting from production of ethylene dichlorides, vinyl chloride, or one or more polymers containing any fraction of polymerized vinyl chloride.

EFFECTIVE DATE: December 23, 1992.

FOR FURTHER INFORMATION: For further information about this correction notice contact Ms. Lynn Hutchinson (919) 541-5624, Standards Development Branch, Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION:**Background**

The regulations that are the subject of this correction notice supersede § 61.60 on the effective date. Section 61.60 deals with the applicability of the regulations for research and

development reactors. The appropriate exemption criteria for a research and development reactor should be equal to 4.17 cubic meters or 1100 gallons. The standard was originally published equating 4.07 cubic meters to 1100 gallons. Effective September 23, 1988 (41 FR 36972), § 61.10 was amended to make the metric units and English units of volume equivalent under the research and development reactor applicability exemption. Since 4.07 cubic meters is actually equal to 1075 gallons, the amendment resolved the inequality by changing the exemption threshold to 4.07 cubic meters or 1075 gallons. However, the appropriate exemption threshold should have remained equal to 1100 gallons, and 4.07 cubic meters should have been changed to 4.17 cubic meters.

Need for Correction

As published, the final regulations contain an error that causes the applicability criteria for a research and development reactor to be more stringent than was originally intended.

List of Subjects in 40 CFR Part 61

Air pollution control, Asbestos, Benzene, Beryllium, Coke oven emissions, Hazardous substances, Incorporation by reference, Inorganic arsenic, Intergovernmental relations, Mercury, Radionuclides, Reporting and recordkeeping requirements, Vinyl chloride, Volatile hazardous air pollutants.

For the reason set out in the preamble, title 40, chapter I, part 61 of the Code of Federal Regulations is amended as follows:

PART 61—NATIONAL EMISSION STANDARD FOR HAZARDOUS AIR POLLUTANTS

1. The authority citation for part 61 continues to read as follows:

Authority: Sections 101, 112, 114, 116, 301 of the Clean Air Act as amended (43 U.S.C. 7401, 7412, 7414, 7416, 7601).

§ 61.60 [Amended]

2. In § 61.60, paragraph (c), the phrase "4.07 m³ (1075 gal)" is revised to read "4.17 m³ (1100 gal)".

Dated: December 11, 1992.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 92-31157 Filed 12-22-92; 8:45 am]

BILLING CODE 8560-50-M

40 CFR Part 180

[OPP-300265A; FRL-4177-4]

RIN 2070-AB78

Ascorbic Acid; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of ascorbic acid (CAS Reg. No. 50-81-7) when used as an inert ingredient (stabilizer and preservative) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. This regulation was requested by Monsanto Co. and DowElanco.

EFFECTIVE DATE: This regulation becomes effective December 23, 1992.

ADDRESSES: Written objections, identified by the document control number, [OPP-300265A], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 219, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-7252.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 28, 1992 (57 FR 48769), EPA issued a proposed rule that gave notice that the Monsanto Co., 700 14th St., NW., Suite 1100, Washington, DC 20005, and DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, had submitted pesticide petitions (PP's) 1E4000 and 2E4136 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)), propose to amend 40 CFR 180.1001(c) by establishing an exemption from the requirement of a tolerance for residues of ascorbic acid (CAS Reg. No. 50-81-7) when used as an inert ingredient (stabilizer and preservative) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as

polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance exemption will protect the public health. Therefore, the tolerance exemption is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections with the Hearing Clerk, at the address given above (40 CFR 178.20). The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant

economic impact on a substantial number of small entities. A certification statement to this effect was published in the *Federal Register* of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 8, 1992.

Douglas D. Camp,
Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001(c) is amended by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert Ingredients	Limits	Uses
Ascorbic acid (CAS Reg. No. 50-81-7)		Stabilizer, preservative

[FR Doc. 92-31009 Filed 12-22-92; 8:45 am]
BILLING CODE 6560-50-F

40 CFR Part 180

[OPP-300266A; FRL-4175-1]

RIN 2070-AB78

Nonyl, Decyl, and Undecyl Glycosides; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of a mixture of nonyl, decyl, and undecyl glycosides when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals. This regulation was requested by the Henkel Corp.

EFFECTIVE DATE: This regulation becomes effective December 23, 1992.

ADDRESSES: Written objections, identified by the document control number, [OPP-300266A], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Kerry B. Leifer, Registration Support Branch, Registration Division (H7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 711L, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-5180.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of October 21, 1992 (56

FR 48009), EPA issued a proposed rule that gave notice that at the request of the Henkel Corp., 300 Brookside Ave., Ambler, PA 19002, the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), had proposed to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of a nonyl, decyl, and undecyl glycoside mixture when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals.

Inert ingredients are all active ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerances will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the *Federal Register*, file written objections with the Hearing Clerk, at the address given above (40 CFR 178.20). The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification

statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 8, 1992.

Douglas D. Campt,
Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.1001 by amending paragraphs (c) and (e) by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert Ingredients	Limits	Uses
Nonly, decyl, and undecyl glycoside mixture with a mixture of nonly, decyl, and undecyl oligosaccharides and related reaction products (primarily decanol and undecanol) produced as an aqueous-based liquid (50 to 65 percent solids) from the reaction of primary alcohols (containing 15 to 20 percent secondary alcohol isomers) in a ratio of 20 percent C ₉ , 40 percent C ₁₀ , and 40 percent C ₁₁ with carbohydrates (average glucose to alkyl chain ratio 1.3 to 1.8).		Surfactant

* * * * *

(e) * * *

Inert Ingredients	Limits	Uses
Nonly, decyl, and undecyl glycoside mixture with a mixture of nonly, decyl, and undecyl oligosaccharides and related reaction products (primarily decanol and undecanol) produced as an aqueous-based liquid (50 to 65 percent solids) from the reaction of primary alcohols (containing 15 to 20 percent secondary alcohol isomers) in a ratio of 20 percent C ₉ , 40 percent C ₁₀ , and 40 percent C ₁₁ with carbohydrates (average glucose to alkyl chain ratio 1.3 to 1.8).		Surfactant

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BILLING CODE 6560-50-F

40 CFR Part 180

[OPP-300259A; FRL-4172-6]
RIN 2070-AB78

Alkyl Acrylate/Methacrylate Copolymers; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of certain copolymers when used as inert ingredients (controlled-release agents) in pesticide formulations applied to growing crops, raw agricultural commodities, and animals. This regulation was requested by Landec Corp.

EFFECTIVE DATE: This regulation becomes effective December 23, 1992.

ADDRESSES: Written objections, identified by the document control number, [OPP-300259A], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Kerry B. Leifer, Registration Support Branch, Registration Division (H7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 7111, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-5180.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 16, 1992 (57 FR 42727), EPA issued a proposed rule that gave notice that the Landec Corp., 3603 Haven Ave., Menlo Park, CA 94025, had requested that the

Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)), propose to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of tetradecyl acrylate-acrylic acid copolymer, hexadecyl acrylate-acrylic acid copolymer, octadecyl acrylate-acrylic acid copolymer, docosyl methacrylate-acrylic acid copolymer, hexadecyl acrylate-butyl acrylate-acrylic acid copolymer, hexadecyl acrylate-dodecyl acrylate-acrylic acid copolymer, octadecyl methacrylate-butyl acrylate-acrylic acid copolymer, octadecyl methacrylate-hexyl acrylate-acrylic acid copolymer, octadecyl acrylate-dodecyl acrylate-acrylic acid copolymer, octadecyl methacrylate-dodecyl acrylate-acrylic acid copolymer, octadecyl methacrylate-dodecyl methacrylate-acrylic acid copolymer,

and docosyl methacrylate-octadecyl methacrylate-acrylic acid copolymer when used as inert ingredients (controlled-release agents) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, or animals.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 152.3(m), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be biologically active.

The Agency received a comment which stated that the value of the minimum average molecular weight given in the proposed rule was in error. The commenter noted that the range of number average molecular weight for the 12 alkyl acrylate/methacrylate copolymers is 3,000 - 80,000; therefore, the minimum number average molecular weight specified in the proposed rule should be 3,000 rather than 20,000. The Agency agrees with the commenter. This correction does not materially affect the basis for the establishment of the tolerance exemption because the Agency has modified § 180.1112 of the final rule accordingly.

There were no requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerances will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections with the Hearing Clerk, at the address given above (40 CFR 178.20). The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections

must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 8, 1992.

Douglas D. Campt,
Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1112, to read as follows:

§ 180.1112 Alkyl acrylate/methacrylate copolymers; exemptions from the requirement of a tolerance.

Tetradecyl acrylate-acrylic acid copolymer, hexadecyl acrylate-acrylic acid copolymer, octadecyl acrylate-acrylic acid copolymer, docosyl methacrylate-acrylic acid copolymer, hexadecyl acrylate-butyl acrylate-acrylic acid copolymer, hexadecyl acrylate-dodecyl acrylate-acrylic acid copolymer,

octadecyl methacrylate-butyl acrylate-acrylic acid copolymer, octadecyl methacrylate-hexyl acrylate-acrylic acid copolymer, octadecyl acrylate-dodecyl acrylate-acrylic acid copolymer, octadecyl methacrylate-dodecyl acrylate-acrylic acid copolymer, octadecyl methacrylate-dodecyl methacrylate-acrylic acid copolymer, and docosyl methacrylate-octadecyl methacrylate-acrylic acid copolymer, minimum number average molecular weight 3,000, are exempted from the requirement of a tolerance when used as inert ingredients (controlled-release agents) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, or animals.

[FR Doc. 92-31011 Filed 12-22-92; 8:45 am]
BILLING CODE 6560-50-F

40 CFR Part 180

[PP OF3885/R1170; FRL-4170-5]

RIN 2070-AB78

Pseudomonas Cepacia Type Wisconsin; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the biological pesticide *Pseudomonas cepacia* type Wisconsin in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices. This exemption was requested by Stine Microbial Products.

EFFECTIVE DATE: This regulation becomes effective December 23, 1992.

ADDRESSES: Written objections, identified by the document control number, [PP OF3885/R1170], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Susan T. Lewis, Product Manager (PM) 21, Registration Division (H7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-557-6900.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 3, 1991 (56 FR 13642), EPA issued a notice that Stine Microbial Products, 4722 Pfaff Rd.,

Madison, WI 53704, had submitted pesticide petition (PP) 0F3885 to EPA, proposing to amend 40 CFR part 180 by establishing a regulation pursuant to the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 346a and 371), to exempt from the requirement of a tolerance the residues of the biological pesticide *Pseudomonas cepacia* type Wisconsin in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices.

There were no comments received in response to the notice.

The organism is a naturally occurring biotype of the bacterial species *Pseudomonas cepacia* which is found world-wide. The original isolates of *Pseudomonas cepacia* type Wisconsin were identified as colonizers of the roots and rhizospheres of maize. Further testing indicated that this biotype will colonize roots of many crop plants. *Pseudomonas cepacia* type Wisconsin has been shown to produce antibiotics which are effective against a diverse range of plant pathogenic fungi. *Pseudomonas cepacia* is not generally regarded as a human or animal pathogen. Products containing this organism are intended to be used for formulating other end-use products or as a seed treatment. When applied to seeds, the bacteria colonize the developing root system, and by producing antibiotics, protect the seedling from a range of plant pathogenic fungi and nematodes.

The data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the exemption from the requirement of a tolerance include an acute oral toxicity/pathogenicity study, an acute dermal toxicity study, an acute pulmonary toxicity/pathogenicity study, and an acute intravenous toxicity/pathogenicity study. All studies were conducted with the rat as the test animal. A review of these studies indicated that the organism was not toxic to test animals when administered via dermal and intravenous routes. The active ingredient was not infective or pathogenic to test animals when administered via the oral, pulmonary, or intravenous route. No reports of hypersensitivity have been recorded from personnel working with this organism. All of the toxicity studies submitted are considered acceptable. The toxicity data provided are sufficient to show that there are no foreseeable health hazards to humans or domestic animals likely to arise from the use of this organism as a seed treatment.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this petition because the data submitted demonstrated that this biological control agent is not toxic to humans. No enforcement actions are expected. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request. This is the first exemption from the requirement of a tolerance for this biological control agent.

Pseudomonas cepacia type Wisconsin is considered useful for the purposes for which the exemption from the requirement of a tolerance is sought. Based on the information considered, the Agency concludes that establishment of a tolerance is not necessary to protect the public health. Therefore, the regulation is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above (40 CFR 178.20). The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant

economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 8, 1992.

Douglas D. Campt,
Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By adding new § 180.1115, to read as follows:

§ 180.1115 *Pseudomonas cepacia* type Wisconsin; exemption from the requirement of a tolerance.

The biological pesticide *Pseudomonas cepacia* type Wisconsin is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices.

[FR Doc. 92-31012 Filed 12-22-92; 8:45 am]
BILLING CODE 6560-50-F

40 CFR Part 271

[FRL-4548-2]

Michigan: Schedule of Compliance for Modification of Michigan's Hazardous Waste Program

AGENCY: Environmental Protection Agency, (EPA).

ACTION: Notice of Michigan's compliance schedule to adopt program modifications.

SUMMARY: On September 22, 1986, the Environmental Protection Agency promulgated amendments to the deadlines for modifications to State Resource Conservation and Recovery Act (RCRA) programs and published requirements for States to be placed on a compliance schedule to adopt necessary program modifications. EPA is today publishing a compliance schedule for Michigan to modify its program in accordance with § 271.21(g) to adopt Federal program modifications
EFFECTIVE DATE: December 23, 1992.

FOR FURTHER INFORMATION CONTACT:

Judy Feigler, Michigan Regulatory Specialist, RCRA Program Management Branch, U.S. Environmental Protection Agency, Region V, HRM-7J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-4179.

SUPPLEMENTARY INFORMATION:**A. Background**

Final authorization to implement the Michigan hazardous waste program within the State in lieu of the Federal RCRA program is granted by U.S. EPA if the Agency finds the State program: (1) is "equivalent" to the Federal program; (2) is "consistent" with the Federal program and other State programs; and (3) provides for adequate enforcement (Section 3006(b), 42 U.S.C. 6926(b)). U.S. EPA regulations for final authorization appear at 40 CFR 271.1-271.25. In order to retain authorization, a State must revise its program to adopt new Federal requirements by the cluster deadlines and procedures specified in 40 CFR 272.21. See 51 FR 33712, September 22, 1986, for a complete discussion of these procedures and deadlines.

B. Michigan

Michigan received final authorization of its hazardous waste program on October 30, 1988 (see 51 FR 36804, October 16, 1986), and subsequent revisions on January 23, 1990 (see 54 FR 48608, November 24, 1989), and June 24, 1991 (see 56 FR 18517, April 23, 1991). On August 12, 1992, Michigan submitted a request under the provisions of 40 CFR 271.21(g)(1)(iii) for an extension of time to obtain necessary program revisions contained in RCRA Cluster 1. Today, U.S. EPA is publishing a compliance schedule pursuant to 40 CFR 271.21(g)(1)(v) for Michigan to complete program revisions for the following Federal RCRA Cluster 1 regulations:

1. Petroleum Refinery Primary and Secondary Oil/Water/Solids Separation Sludge Listings (F037 and F038), 55 FR 46354, November 2, 1990;
2. Wood Preserving Listings, 55 FR 50450, December 6, 1990;
3. Petroleum Refinery Primary and Secondary Oil/Water/Solids Separation Sludge Listings; Correction, 55 FR 51707, December 17, 1990;
4. Land Disposal Restrictions for Third Scheduled Wastes; Technical Correction, 56 FR 3864, January 31, 1991;
5. Toxicity Characteristic; Hydrocarbon Recovery Operations, 56 FR 3978, February 1, 1991;

6. Burning of Hazardous Waste in Boilers and Industrial Furnaces, 56 FR 7134, February 21, 1991;

7. Removal of Strontium Sulfide from the List of Hazardous Waste; Technical Amendment, 56 FR 7567, February 25, 1991;

8. Toxicity Characteristic; Hydrocarbon Recovery Operations, 56 FR 13406, April 2, 1991;

9. Organic Air Emission Standards for Process Vents and Equipment Leaks; Technical Amendment, 56 FR 19290, April 26, 1991;

10. Mining Exclusion III, 56 FR 27300, June 13, 1991;

The deadline under 40 CFR 271.21 for Michigan to adopt the Federal RCRA Cluster 1 regulations was July 1, 1992. However, the State's work on RCRA Cluster 1 rulemaking was postponed until after the State could finish promulgating rules for non-HSWA Clusters V and VI and HSWA Clusters I and II.

The State has agreed to complete the needed program revisions to its authorized program according to the following schedule:

1. The Department of Natural Resources will open public comment on the draft rules package by August 1, 1993. The comment period will end on September 15, 1993.

2. Once the proposed rule package is approved by the Michigan Legislative Service Bureau, the Michigan Attorney General, and the Michigan Joint Committee on Administrative Rules, the rules will be submitted to the Michigan Secretary of State for codification in the Act 64 Administrative Rules. The State expects to complete this process and finally adopt the rules by December 31, 1993.

4. Michigan expects to submit an application to U.S. EPA requesting authorization for the Federal regulations listed above by March 1, 1994.

Authority: This notice is issued under the authority of Sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended by the RCRA of 1976, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: December 9, 1992.

William H. Sanders III,

Acting Regional Administrator.

[FR Doc. 92-31153 Filed 12-22-92; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 300

[FRL-4545-6]

National Oil and Hazardous Substances Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of a site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Metal Working Shop Superfund Site in Lake Ann, Michigan from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the State of Michigan have determined that all appropriate Fund-financed responses under CERCLA have been implemented and that no further cleanup by responsible parties is appropriate. Moreover, EPA and the State of Michigan have determined that no remedial action is necessary at the site. The response is protective of public health, welfare, and the environment.

EFFECTIVE DATE: December 23, 1993.

FOR FURTHER INFORMATION CONTACT:

Samuel Borries, Remedial Project Manager, U.S. Environmental Protection Agency, Region V, 77 W. Jackson Boulevard, Chicago, Illinois 60604, (312) 353-3156. Phillip Schutte, Office of Public Affairs, U.S. Environmental Protection Agency, Region V, 77 W. Jackson Boulevard, Chicago, Illinois 60604, (312) 353-8685.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Metal Working Shop, Lake Ann, Michigan.

A notice of intent to delete the site was published September 10, 1992 (57 FR 41452). The closing date for comments on the Notice of Intent to Delete was October 13, 1992. EPA received no comments and will therefore prepare no responsiveness summary.

The EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substances Response Trust Fund (Fund-) financed remedial actions. Any site deleted from the NPL remains eligible for Fund-financed remedial action in the unlikely event that conditions at the site warrant such action. Section 300.425(e) of the NCP states that Fund-financed actions

may be taken at sites deleted from the NPL.

Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Hazardous waste.

Dated: November 17, 1992.

Valdas V. Adamkus,
Regional Administrator, USEPA Region V.

For the reasons set out in the preamble 40 CFR, part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9601-9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

2. Table 1 of appendix B to part 300 is amended by removing the site for "Metal Working Shop, Lake Ann, Michigan".

3. The total number of sites in Table 1, of Appendix B to part 300, "1085" is revised to read "1084".

[FR Doc. 92-30509 Filed 12-22-92; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 300

[FRL-4545-7]

National Oil and Hazardous Substances Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of a site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the ARRCOM site in Rathdrum, Idaho from the National Priorities List (NPL). The NPL is appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the State of Idaho have determined that all appropriate Fund-financed responses under CERCLA have been implemented and that no further cleanup by responsible parties is appropriate. Moreover, EPA and the

State of Idaho have determined that remedial actions conducted at the site to date have been protective of public health, welfare, and the environment.

EFFECTIVE DATE: December 23, 1992.

FOR FURTHER INFORMATION CONTACT: Fran Allans, Remedial Project Manager, U.S. Environmental Protection Agency, Region 10, 422 W. Washington, Boise, Idaho 83702, (208) 334-9047.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: ARRCOM, Rathdrum, Idaho.

A notice of intent to delete for this site was published October 2, 1992 (57 FR 45599). The closing date for comments on the Notice of Intent to Delete was November 2, 1992. EPA received no comments.

EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substance Response Trust Fund-financed remedial actions. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.66(c)(8) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Hazardous waste.

Dated: November 16, 1992.

Dana A. Rasmussen,
Regional Administrator, U.S. EPA Region 10.

For the reasons set out in the preamble 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: U.S.C. 9601-9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

2. Table 1 of Appendix B to part 300 is amended by removing the site for "ARRCOM (Drexler Enterprises), Rathdrum, Idaho."

3. The total number of sites in Table 1 of Appendix B to part 300, "1084" is revised to read "1083".

[FR Doc. 92-30510 Filed 12-22-92; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 52a

RIN 0905-AC27

National Institutes of Health Center Grants

AGENCY: Public Health Service, HHS.

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH) is amending its center grant regulations to: indicate their general applicability to all center grant programs statutorily authorized in title IV of the Public Health Service (PHS) Act; incorporate program changes and changes in PHS Act section numbers which resulted from the enactment of the Health Research Extension Act of 1985 (Pub. L. 99-158), the National Deafness and Other Communication Disorders Act of 1988 (Pub. L. 100-553), and the Health Omnibus Programs Extension of 1988 (Pub. L. 100-607); and make minor language and technical changes.

EFFECTIVE DATE: Effective December 23, 1992.

FOR FURTHER INFORMATION CONTACT: John Migliore, NIH Regulations Officer, National Institutes of Health, Building 31, room 3B-11, Bethesda, Maryland 20892—telephone (301) 496-4606. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: Regulations governing National Institutes of Health (NIH) center grants were published in the Federal Register on December 4, 1985 (50 FR 49692). On November 20, 1985, the Health Research Extension Act of 1985 (Pub. L. 99-158) was enacted, reauthorizing the authorities and programs of the National Institutes of Health. As a result of the law, the sections of the PHS Act that authorized various center grant programs were renumbered, thus requiring a change of the legal citations in the "Authority" section of these regulations. Later, Public Laws 100-553 and 100-607 were enacted, authorizing new center grants programs. The NIH is amending the current regulations at 42 CFR part 52a to incorporate these changes into its center grants regulations.

In addition, since the basic policies governing the award of center grants under the authorities of sections 414, 422, 431, 441, 445, 445A, 464, and 23216 of the PHS Act are substantially similar, the NIH is revising its current regulations to encompass all center

grant programs authorized statutorily in title IV of the PHS Act including: Alzheimer's Disease Research Centers; Centers for Acquired Immunodeficiency Syndrome Research; Diabetes Research and Training Centers; Claude D. Pepper Older Americans Independence Centers; Kidney and Urologic Diseases Centers; Multipurpose Arthritis and Musculoskeletal Diseases Centers; Multipurpose Deafness and Other Communication Disorders Centers; National Cancer Research and Demonstration Centers; National Research and Demonstration Centers for Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources; and National Research and Demonstration Centers for Sickle Cell Anemia.

The NIH is also revising its current regulations to include references to several additional HHS policies and regulations affecting its center grant regulations. Section 52a.8 is being revised to include:

(1) References to new HHS regulations at 42 CFR part 50, subpart A, regarding the responsibilities of PHS awardees and applicant institutions for dealing with and reporting possible misconduct in science published on August 8, 1989 (54 FR 32446);

(2) New HHS regulations at 45 CFR part 93 regarding new restrictions on lobbying published on February 26, 1990 (55 FR 6736);

(3) New HHS regulations at 45 CFR part 76, subpart F, on drug-free workplace requirements published on May 25, 1990 (55 FR 21677); and

(4) PHS policy on humane care and use of laboratory animals.

As stated in section 52a.1, this final rule does not apply to grants for construction, unless specifically noted, traditional research projects, or general research support. Although certain types of research project grants have been commonly referred to as "center grants," those grants differ from the support programs specifically authorized by sections 414, 422, 431, 441, 445, 464, and 2316 the PHS Act and are governed by the research project grant regulations at 42 CFR part 52.

This final rule does not repeat provisions of the authoring legislation, and thus must be read in conjunction with the cited sections of the PHS Act, as appropriate for the particular center grants program.

The NIH announced its intention to amend the regulations at 42 CFR part 52a and invited public comment on the regulations in a Notice of Proposed Rulemaking published in the Federal Register on May 13, 1991 (56 FR 21974). The public was given 60 days to comment. No comments were received.

Consequently, these final regulations are, except for minor editorial changes, the same as the proposed regulations.

Information Collection Requirements

Sections 52a.4 and 52a.6 of this final rule contain information collections which are subject to OMB approval under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35). The information collections have been approved by OMB under OMB Control No. 0925-0001. The applications (Standard Form PHS 398 Application for Public Health Service Grant and PHS 2590 Application for Continuation of Public Health Service Grant) used in the information collections specified in sections 52a.4 and 52a.6 and the burden hours associated with the application requirements in these regulations are included with the approval of the applications in OMB Control No. 0925-0001.

Regulatory Impact and Regulatory Flexibility Analysis

This final rule extends existing policies and procedures governing the award and administration of discretionary grants to eligible institutions to support certain health research centers. While these centers benefit those segments of the public afflicted by the health problems addressed by the centers, and physicians and other health professionals who receive training in those health areas, the centers do not have a significant economic or policy impact on a broad cross-section of the public. Therefore, the Secretary has determined that the regulations do not constitute a "major rule" as defined under Executive Order No. 12291. Furthermore, these regulations only affect those few institutions interested in obtaining assistance to carry out a center's authorized programs, subject to the normal accountability requirements for grant funds. No entity is obligated to apply for grant support.

Additionally, the Secretary has determined that this final rule does not have a significant economic impact on a substantial number of small entities, and therefore does not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6).

Family and Federalism Impact

This final rule has been reviewed under the requirements of Executive Order 12606, "The Family", and Executive Order 12612, "Federalism", and the Secretary has determined that it will not have a significant potential negative impact on family well-being.

States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbered programs affected by this final rule are:

- 93.173 Multipurpose Deafness and Other Communication Disorders Centers;
- 93.397 Cancer Centers Support;
- 93.837 Heart and Vascular Diseases Research;
- 93.838 Lung Diseases Research;
- 93.839 Blood Diseases and Resources Research;
- 93.846 Arthritis, Musculoskeletal, and Skin Diseases Research;
- 93.847 Diabetes, Endocrinology, and Metabolism Research;
- 93.848 Digestive Diseases and Nutrition Research;
- 93.849 Kidney Diseases, Urology and Hematology Research;
- 93.855 Allergy, Immunology, and Transplantation Research; and
- 93.866 Aging Research.

List of Subjects in 42 CFR Part 52a

Acquired Immunodeficiency Syndrome; Alzheimer's disease; Arthritis; Cancer; Diabetes; Grant programs-Health; Medical research; Sickle Cell Anemia.

For the reasons set out in the preamble, subchapter D of chapter 1 of title 42 of the Code of Federal Regulations, part 52a, is revised to read as set forth below.

Dated: November 29, 1991.

James O. Mason,
Assistant Secretary for Health.

Approved: January 28, 1992.

Louis W. Sullivan,
Secretary.

Editorial Note: This document was received at the Office of the Federal Register December 18, 1992.

PART 52a—NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Sec.

- 52a.1 To which programs do these regulations apply?
- 52a.2 Definitions.
- 52a.3 Who is eligible to apply?
- 52a.4 What information must each application contain?
- 52a.5 How will NIH evaluate applications?
- 52a.6 Information about grant awards.
- 52a.7 For what purposes may a grantee spend grant funds?
- 52a.8 Other HHS regulations that apply.
- 52a.9 Additional conditions.

Authority: 42 U.S.C. 216, 285a-3, 285b-4, 285c-5, 285d-6, 285e-2, 285e-3, 285m-3, and 300cc-16.

§ 52a.1 To which programs do these regulations apply?

(a) This part applies to grants by the National Institutes of Health and its organizational components to support the planning, establishment, expansion and operation of research and demonstration, multipurpose, and other centers. Specifically, this part applies to National Cancer Research and Demonstration Centers (including payments for construction), as authorized by section 414 of the Act; National Research and Demonstration Centers for Heart, Blood Vessel, Lung, and Blood Diseases, Sickle Cell Anemia, and Blood Resources (including payments for construction), as authorized by section 422 of the Act; Research and Training Centers (including diabetes mellitus, and digestive, endocrine, metabolic, kidney and urologic diseases), as authorized by section 431 of the Act; Multipurpose Arthritis and Musculoskeletal Disease Centers (including payments for alteration, but not construction), as authorized by section 441 of the Act; Alzheimer's Disease Centers, as authorized by section 445 of the Act; Claude D. Pepper Older Americans Independence Centers, as authorized by section 445A of the Act; Multipurpose Deafness and Other Communication Disorders Centers, as authorized by section 464C of the Act; and Centers for Acquired Immunodeficiency Syndrome Research, as authorized by section 2316 of the Act.

This part does not apply to:

- (1) Grants for construction (see 42 CFR part 52b), except as noted above;
- (2) Grants covered by 42 CFR part 52 (grants for research projects); or
- (3) Grants for general research support under section 301(a)(3) of the Act (42 U.S.C. 241(a)(3)).

(b) This part also applies to cooperative agreements made to support the centers specified in paragraph (a) of this section. When a reference is made in this part to "grants," the reference shall include "cooperative agreements."

§ 52a.2 Definitions.

As used in this part:

"Act" means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

"Center" means:

(1) For purposes of grants authorized in section 414 of the Act, an agency or institution which provides for planning and conducting basic and clinical research into, training in, and demonstration of advanced diagnostic, control, prevention and treatment methods for cancer;

(2) For purposes of grants authorized in section 422 of the Act, an agency or institution which provides for planning and basic and clinical research into, training in, and demonstration of, management of blood resources and advanced diagnostic, prevention, and treatment methods (including emergency medical services) for heart, blood vessel, lung, or blood diseases, including sickle cell anemia;

(3) For purposes of grants authorized in section 431 of the Act, a single institution or a consortium of cooperating institutions, which conducts research, training, information programs, epidemiological studies, data collection activities, and development of model programs in diabetes mellitus and related endocrine and metabolic diseases;

(4) For purposes of grants authorized in section 441 of the Act, a facility which conducts basic and clinical research as well as research into arthritis and musculoskeletal diseases, orthopedic procedures, training, and information programs for the health community and the general public;

(5) For purposes of grants authorized in section 445 of the Act, an agency or institution (including university medical centers) which conducts basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease;

(6) For purposes of grants authorized in section 445A of the Act, an agency or institution which conducts: (i) Research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals; and (ii) programs to develop individuals capable of conducting such research;

(7) For purposes of grants authorized in section 464C of the Act, a single institution or a consortium of cooperating institutions which conducts basic and clinical research into, training in, information and continuing education programs for the health community and the general public about, and demonstration of advanced diagnostic, prevention, and treatment methods for, disorders of hearing and

other communication processes and complications resulting from such disorders; or

(8) For purposes of grants authorized in section 2316 of the Act, an entity for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immunodeficiency.

As required in a section of the Act cited in this part or at the determination of the Director of the NIH awarding organizational component, a center may include the facilities of a single institution or a consortium of cooperating institutions and, if practical, may be part of an equitable geographical distribution of centers, or an environment with proven research capabilities.

"NIH" means the National Institutes of Health and its organizational components that award grants.

"Nonprofit" as applied to any agency or institution means an agency or institution which is a corporation or an association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

§ 52a.3 Who is eligible to apply?

(a) Any public or private non-profit agency, institution, or consortium of agencies or institutions is eligible to apply for a grant under sections 414, 422, 441, 445, and 445A and 2316 of the Act.

(b) Any public or private non-profit or for-profit agency, institution or consortium of agencies or institutions is eligible to apply for a grant under sections 431 and 464C of the Act.

(c) Any applicant under this part must be located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the successor States of the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

§ 52a.4 What information must each application contain?

Each application under this part must include detailed information as to the following:

(a) The personnel, facilities, and other resources available to the applicant with which to initiate and maintain the proposed center grants program;

(b) Any research, training, demonstration, or information dissemination activities in which the applicant is currently engaged; the sources of funding for these activities; and the relevance of these activities to the proposed center grants program;

(c) Proposed research, training, demonstration, and information dissemination activities;

(d) The proposed organizational structure of the center and the relationship of the proposed center to the applicant organization(s);

(e) The names and qualifications of the center director and key staff members who would be responsible for conducting the proposed activities;

(f) Proposed methods for monitoring and evaluating individual activities and the overall center program;

(g) Proposed methods for coordinating the center's activities, where appropriate, with similar efforts by other public and private organizations;

(h) The availability of any community resources necessary to carry out proposed activities; and

(i) Efforts to be made to generate and collect income from sources other than NIH to be used to further the purposes of the center program. NIH encourages these efforts. Income may include, but is not limited to, that generated from the sale or rental of products or services produced by grant-supported activities, such as laboratory tests, computer time, and payments received from patients or third parties, where appropriate (the disposition of grant-related income is governed by 45 CFR 74.40 through 74.47 and 45 CFR 92.25);

(j) The proposed budget for the center and a justification for the amount of the grant funds requested; and

(k) Any other information that the Director of the awarding institute may request.

[Approved under OMB Control Number 0925-0001]

§ 52a.5 How will NIH evaluate applications?

(a) NIH considers the following in evaluating Center grant applications:

(1) The scientific and technical merit of the proposed program;

(2) The qualifications and experience of the center director and other key personnel;

(3) The statutory and program purposes to be accomplished;

(4) The extent to which the various components of the proposed program would be coordinated into one multi-disciplinary effort within the center;

(5) The extent to which the center's activities would be coordinated with similar efforts by other organizations;

(6) The administrative and managerial capability of the applicant;

(7) The reasonableness of the proposed budget in relation to the proposed program; and

(8) Other factors which the awarding institute, center, or division considers

appropriate in light of its particular statutory mission.

(b) Where required by statute or NIH policy, applications are reviewed by appropriate national advisory councils or boards before awards are made. NIH grants may be awarded generally only after approval recommendations from both appropriate scientific peer review groups and national advisory councils or boards.

§ 52a.6 Information about grant awards.

(a) The notice of grant award specifies how long NIH intends to support the project without requiring the project to re-compete for funds. This period, called the project period, will usually be for 1-5 years.

(b) Generally, the grant will initially be for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the NIH that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application, nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

[Approved under OMB Control Number 0925-0001]

§ 52a.7 For what purposes may a grantee spend grant funds?

A grantee shall only spend funds it receives under this part according to the approved application and budget, the authorizing legislation, the terms and conditions of the award, the applicable cost principles prescribed in subpart Q of 45 CFR part 74 and 45 CFR 92.22, and the regulations of this part.

§ 52a.8 Other HHS regulations that apply.

Several other regulations and policies apply to this part. These include, but are not necessarily limited to:

42 CFR Part 50, Subpart A—

Responsibilities of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedures

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures

45 CFR Part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under part 80 of this title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments

45 CFR Part 93—New restrictions on lobbying

51 FR 16958 or successor—NIH Guidelines for Research Involving Recombinant DNA Molecules

Public Health Service Policy on Humane Care and Use of Laboratory Animals.

§ 52a.9 Additional conditions.

NIH may, with respect to any grant award, impose additional conditions prior to or at the time of any award when, in NIH's judgment, the conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

[FR Doc. 92-31105 Filed 12-22-92; 8:45 am]

BILLING CODE 4140-01-M