

DEPARTMENT OF DEFENSE

GENERAL SERVICES
ADMINISTRATIONNATIONAL AERONAUTICS AND
SPACE ADMINISTRATION

48 CFR Part 30

Federal Acquisition Regulation (FAR);
Cost Accounting Standards

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council are considering changes to Federal Acquisition Regulation (FAR) 30.404-40(b)(1), 30.404-60(a)(1), and 30.404-60(a)(1)(i) which will increase the minimum acquisition cost criterion for capitalization purposes from \$1,000 to \$1,500.

DATE: Comments should be submitted to the FAR Secretariat at the address shown below on or before September 8, 1986, to be considered in the formulation of a final rule.

ADDRESS: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets NW, Room 4041, Washington, DC 20405.

Please cite FAR Case 86-35 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret A. Willis, FAR Secretariat, Telephone (202) 523-4755.

SUPPLEMENTARY INFORMATION:**A. Background**

The Cost Accounting Standards (CAS) are being proposed for incorporation into the FAR under FAR Case 86-31. This proposal represents the second proposed revision to the standards

originally promulgated by the Cost Accounting Standards Board. The revision being proposed in this notice will not be implemented until the revision proposed under FAR Case 86-31 (51 FR 20238, June 3, 1986) are adopted in a final rule.

FAR 30.404-40(b)(1) provides that a contractor's capitalization policy shall designate a minimum service life criterion, which shall not exceed two years, and a minimum acquisition cost criterion, which shall not exceed \$1,000. The proposed rule increases the minimum acquisition cost criterion from \$1,000 to \$1,500 due to the impact of inflation. The purpose of the change is to only require capitalization of those assets that are of significant value.

B. Regulatory Flexibility Act

The proposed revisions to FAR 30.404(b)(1), 30.404-60(a)(1), and 30.404-60(a)(1)(i) will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.) because the changes cover Cost Accounting Standards from which small business concerns are exempt.

C. Paperwork Reduction Act

The proposed revisions to FAR 30.404(b)(1), 30.404-60(a)(1), and 30.404-60(a)(1)(i) increase the minimum acquisition cost criterion for capitalization purposes from \$1,000 to \$1,500. The rule does not change or otherwise affect the collection of information by Federal agencies from offerors, contractors, or members of the public.

List of Subjects in 48 CFR Part 30

Government procurement.

Dated: June 30, 1986.

Lawrence J. Rizzi,

Director, Office of Federal Acquisition and Regulatory Policy.

**PART 30—COST ACCOUNTING
STANDARDS**

Therefore, it is proposed that 48 CFR Part 30 be amended as set forth below:

1. The authority citation for Part 30 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c).

2. Section 30.404-40 is amended by revising paragraph (b)(1) to read as follows:

30.404-40 Fundamental requirement.

* * * * *

(b) * * *

(1) The contractor's policy shall designate a minimum service life criterion, which shall not exceed two years, but which may be a shorter period. The policy shall also designate a minimum acquisition cost criterion which shall not exceed \$1,500, but which may be a smaller amount.

* * * * *

3. Section 30.404-60 is amended by revising paragraphs (a)(1) and (a)(1)(i) to read as follows:

30.404-60 Illustrations.

(a) * * * (1) Contractor has an established policy of capitalizing tangible assets which have a service life of more than one year and a cost of \$2,000. The contractor's policy must be modified to conform to the \$1,500 policy limitation on minimum acquisition cost established by the Standard.

(i) Contractor acquires a tangible capital asset with a life of 18 months at a cost of \$1,700. The Standard requires that the asset be capitalized in compliance with the contractor's policy as to service life.

* * * * *

[FR Doc. 86-15229 Filed 7-8-86; 8:45 am]

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Best Management Practices

Wednesday
July 9, 1986

Part III

Environmental Protection Agency

40 CFR Parts 405 et al.

Best Conventional Pollutant Control
Technology; Effluent Limitations
Guidelines; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 405, 406, 407, 408, 409, 411, 412, 418, 422, 424, 426, and 432

[FRL 2941-9]

Best Conventional Pollutant Control Technology; Effluent Limitations Guidelines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes effluent limitations guidelines based on the application of the best conventional pollutant control technology (BCT) for the discharge of conventional pollutants into navigable waters by certain industrial dischargers and also establishes the Agency's general methodology for determining the reasonableness of costs for these, subsequent BCT effluent limitations guidelines, and case by case determinations of BCT effluent limitations in discharge permits under section 402(a)(1) of the Clean Water Act. This action responds to a judicial remand of a final regulation promulgated in August 1979. The effect of this action is to codify BCT effluent limitations guidelines for dischargers in the following industries: Dairy Products Processing, Grain Mills, Fruits and Vegetables Processing, Seafood Processing, Sugar Processing, Cement Manufacturing, Phosphate Manufacturing, Ferroalloy Manufacturing, Glass Manufacturing, and Meat Products.

DATES: This regulation becomes effective August 22, 1986. In accordance with 40 CFR 23.50 (FR 7268), this regulation shall be considered issued for purposes of judicial review at 1:00 p.m. Eastern time on July 23, 1986. Under section 509(b)(2) of the Clean Water Act, judicial review of these regulations and the BCT methodology published today can be made only by filing a petition for review in the United States Court of Appeals within 90 days after the regulation is considered issued for purposes of judicial review. Under section 509(b)(2) of the Clean Water Act, the requirements in this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements. Application of the BCT methodology can be challenged in a subsequent rulemaking and in any case-by-case determinations in permit proceedings.

ADDRESSES: The Record for the final rule is available for public inspection in

EPA's Public Information Reference Unit, located in the EPA Library, Room 2404, 401 M Street, SW., Washington, DC. The EPA public information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Ms. Debra Maness, (202) 382-5385.

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I. Background

A. Definition and Legal Basis

In 1977, Congress amended the Clean Water Act to include section 304(b)(4), which instructs EPA to establish effluent limitations guidelines based on the application of the "best conventional pollutant control technology" (BCT) for existing industrial point sources that discharge conventional pollutants. The BCT effluent limitations guidelines are not additional guidelines, but instead, replace guidelines based on the application of the "best available technology economically achievable" (BAT) for the control of conventional pollutants. BAT effluent limitations guidelines remain in effect for nonconventional and toxic pollutants.

Effluent limitations based on BCT may not be less stringent than the limitations based on "best practicable control technology currently available" (BPT). Thus, BPT effluent limitations guidelines are a "floor" below which BCT effluent limitations guidelines cannot be established.

Section 304(b)(4)(B) adds an additional evaluation to the effluent limitations guidelines process for conventional pollutants. In addition to the Clean Water Act requirement that effluent limitations guidelines be economically achievable, the cost associated with the BCT effluent limitations guidelines must also be "reasonable" in relation to the effluent pollutant reductions. The evaluation concerning the reasonableness of BCT also applies to effluent limitations in permits prepared under the National Pollutant Discharge Elimination System (NPDES). Thus, throughout this preamble, the use of the term "effluent limitations" means effluent limitations guidelines for industrial categories and effluent limitations established on a case by case basis in permits. The Agency will also prepare permit-writing guidance on the subject of BCT effluent limitations.

In establishing BCT effluent limitations, section 304(b)(4)(B) states that EPA must consider

... the reasonableness of the relationship between the costs of attaining a reduction in effluents and the effluent reduction benefits derived, and the comparison of the cost and level of reduction of such pollutants from the discharge from publicly owned treatment works to the cost and level of reduction of such pollutants from a class or category of industrial sources ...

The procedure EPA uses to account for these factors is known as the BCT methodology. Stated intuitively, the BCT methodology answers the question of whether it is "cost-reasonable" for industry to control conventional pollutants at a level more stringent than BPT effluent limitations already require. The Act also specifies that in establishing BCT effluent limitations, consideration be given to the age of equipment, production processes, energy requirements, and other appropriate factors.

In developing the BCT methodology, EPA has been guided both by the statutory language of section 304(b)(4)(B) and by Congress' underlying objectives as expressed in the legislative history of the Clean Water Act. Congress was concerned that the controls for conventional pollutants at levels more stringent than BPT were likely to be unreasonably expensive in

some cases. Accordingly, Congress required that a "cost-reasonableness" comparison be applied before establishing BCT effluent limitations guidelines at a level more stringent than BPT effluent limitations guidelines. The final BCT methodology contained in this regulation satisfies those objectives and, thus, is consistent with the statute and with Congressional intent.

Section 304(a)(4) of the Act specifies the pollutants that are classified as conventional. This section designated the following pollutants as conventional: biochemical oxygen demand (reported as five-day biochemical oxygen demand or BOD₅ and hereafter shown as BOD), total suspended solids (TSS), fecal coliform, and pH. The Administrator designated oil and grease as conventional on July 30, 1979 (44 FR 44501). If pollutants are subsequently added or deleted from the conventional pollutant list, the Agency would then reevaluate all effluent limitations guidelines affected by such revisions.

B. Previous Regulations

Section 73 of the Clean Water Act of 1977 (Pub. L. 95-217) directed EPA to review then existing BAT effluent limitations guidelines for conventional pollutants to determine their suitability as BCT effluent limitations guidelines. The review was intended to cover all industries although the time deadlines for the review were different for different industries. The industries on the list in Table 2 of Congressional Committee Print 95-30 from the Committee on Public Works and Transportation ("Data Relating to H.R. 3199 (Clean Water Act of 1977), November 1977) became known as the primary industries. The industries not included on that list became known as the secondary industries.

On August 29, 1979, EPA published a BCT methodology and promulgated BCT effluent limitations guidelines for 41 subcategories of the secondary industries (44 FR 50732). The focus of the August 1979 rule was the review of existing BAT effluent limitations guidelines for the secondary industries to determine if they satisfied the criteria in section 304(b)(4)(B) for cost-reasonableness. The core of the methodology was a comparison of the costs of removing additional pounds of conventional pollutants for industry to the costs of removing conventional pollutants for an average-sized publicly owned treatment works (POTW).

The cost comparison figure for the POTW constituted the basic measure of "reasonableness," and the BCT test compared this POTW cost to the cost for industry to remove one pound of

conventional pollutants. This BCT test was applied to existing BAT effluent limitations guidelines for conventional pollutants. If the industry cost was lower than the POTW cost, the test was "passed"; that is, the BAT level of control was considered reasonable, and the existing BAT effluent limitations guidelines for conventional pollutants were redesignated as BCT effluent limitations guidelines. If the industry cost was higher than the POTW cost, the test was "failed" and BCT guidelines were not set equivalent to the BAT level. Instead, the existing BAT guidelines for conventional pollutants were withdrawn until appropriate BCT guidelines could be established.

The 1979 regulation was challenged in the U.S. Court of Appeals for the Fourth Circuit, and on July 28, 1981, the Court issued its decision. *American Paper Institute v. EPA*, 660 F.2d 954 (4th Cir. 1981). While upholding the methodology that EPA had developed for the POTW cost comparison test, the Court remanded the regulation to the Agency for two reasons. First, the Court held that the Clean Water Act requires EPA to consider two tests of "reasonableness" as part of the BCT methodology: a POTW cost-comparison test and an industry cost-effectiveness test. Since the 1979 methodology contained only the POTW cost test, the Court directed EPA to develop a separate industry cost-effectiveness test. Second, the Court also remanded the regulation for EPA to correct certain statistical errors that had been made in calculating the POTW test.

As a result of the remand, EPA withdrew many of the BCT effluent limitations guidelines for secondary industries that were promulgated in 1979, and also withdrew BCT effluent limitations guidelines for the Timber Products Processing Point Source Category, which were based on the same methodology (47 FR 6835, February 17, 1982).

On October 29, 1982, EPA proposed a revised BCT methodology (47 FR 49176), responding to the Court's remand by presenting an industry cost-effectiveness test (the "second" test) and by correcting the statistical errors in the prior calculations for the POTW test. The proposal also encompassed the Agency's general re-evaluation of the BCT methodology, conducted in response to a directive from a Presidential Task Force on Regulatory Relief. Based on that review, EPA determined that the POTW cost test promulgated in 1979 and upheld by the Court of Appeals was still the preferred approach, but added an industry cost-effectiveness test. These two tests

continue to be the basis for the final methodology and are described in detail later in this preamble (see Section III).

In the same proposal, EPA published proposed BCT effluent limitations guidelines for the secondary industries, based on the revised methodology. The proposal also addressed some of the primary industries by reproposing existing regulations or replacing withdrawn regulations, as appropriate. In summary, the October 1982 proposal brought all existing BCT regulations into conformance with the revised methodology.

Subsequent to the October 1982 proposal, the Agency issued a notice of availability concerning new cost information on POTWs (48 FR 24742, June 2, 1983). The new data was of the same form as the cost data used in the October 1982 proposal, but it was more current. The Agency believed the new cost data to be the most current information to use in calculating the BCT benchmarks. However, on September 16, 1983, the Agency withdrew the June 1983 notice pending further evaluation of whether the new data were appropriate for use in the BCT methodology (48 FR 44091). During the re-evaluation, the Agency concluded that the data used both at proposal in October 1982 and in the June 1983 notice were unsuitable for the BCT methodology. EPA concluded that it was necessary to use a different source of information for POTW costs. The new approach was to develop POTW model plant costs specifically for the BCT methodology. The model POTW approach and costs were detailed in a notice of data availability on September 20, 1984 (49 FR 37046); the notice also alerted the public to several other possible changes in the BCT methodology.

The Agency received extensive comments on the October 1982 proposal and subsequent, related notices. Some of the major comments are discussed later in this Preamble (see Section IX), and all comments are addressed in the record for this final regulation.

Today's final regulation is the culmination of the notice and comment process. The remainder of this preamble defines the final methodology, describes its development, and presents the results from applying the methodology. Table 1, which is explained in the next section (under Heading II.B), is a summary of the results for 13 industries. The regulations promulgated today establish final BCT effluent limitations guidelines for some of the secondary industries. The BCT methodology described herein will also generally

apply to the primary industries, although final BCT effluent limitations for the primary industries will be published in future rulemakings. EPA also expects to apply today's BCT methodology in all subsequent rulemakings and permit proceedings and so considers the BCT methodology as described in this Federal Register notice final for purposes of judicial review. Application of this methodology can be challenged in subsequent rulemakings and BPT permit proceedings.

II. Summary of Final Rulemaking

A. Application of BCT Methodology

1. Candidate Technologies

Establishing BCT effluent limitations for an industrial category or subcategory begins by identifying technology options that provide additional conventional pollutant control beyond the level of control provided by the application of BPT effluent limitations. Any such "candidate technologies" are then evaluated to determine if they are technologically feasible and economically achievable. The candidate technology must meet these requirements to be considered as a basis for BCT effluent limitations. EPA then evaluates candidate technologies by applying the BCT cost test, which consists of two parts: the POTW test and the industry cost-effectiveness test.

2. POTW Test

To "pass" the POTW test, the cost per pound of conventional pollutant removed by industrial dischargers in upgrading from BPT to the candidate BCT must be less than the cost per pound of conventional pollutant removed in upgrading POTWs from secondary treatment to advanced secondary treatment. The upgrade cost to industry must be less than the POTW benchmark of \$0.25 per pound (in 1976 dollars) for industries whose cost per pound is based on long-term performance data (first tier POTW benchmark), or less than \$0.14 per pound for industries whose cost per pound is not based on long-term performance data (second tier POTW benchmark).

While the preferred approach for applying the BCT methodology is to calculate the cost per pound with long-term performance data, these data are not uniformly available for most of the secondary industries. The costs per pound for industries without long-term performance data are derived from the maximum 30-day limitations that were originally based on the application of BAT, prior to the requirement that the Agency establish BCT effluent

limitations guidelines. Therefore, for purposes of applying the BCT methodology to the industries with this data constraint, a second tier of benchmarks was calculated using the same type of data as is available for the industries without long-term performance data (i.e., 30-day data).

As discussed in Section I, the conventional pollutants are BOD, TSS, oil and grease, fecal coliform, and pH. The pollutants included in calculating the POTW pollutant removal are BOD and TSS. These pollutants are also used to calculate the pollutant removal for a candidate BCT, but oil and grease may be included when appropriate in the context of the industry and technology being evaluated. Fecal coliform and pH are not included in the calculations because control of these pollutants is not measurable as "pounds removed." An acceptable interval for controlling pH is evaluated with respect to the particular processes of a candidate technology. Generally, the acceptable pH interval for BCT will be the same as that for BPT. Maintaining the acceptable interval is an inherent cost of the BCT technology and must be economically achievable and cost-reasonable.

3. Industry Cost-Effectiveness Test

Candidate technologies must also "pass" the industry cost-effectiveness test. For each industry subcategory, EPA computes a ratio of two incremental costs. The first is the cost per pound removed by the BCT candidate technology relative to BPT; the second is the cost per pound removed by BPT relative to no treatment (i.e., the second cost compares raw wasteload to pollutant load after application of BPT).

The ratio of the first cost divided by the second is a measure of the candidate technology's cost-effectiveness. The ratio is compared to an industry cost benchmark, which again is based on POTW cost and pollutant removal data. The benchmark, like the measure for a candidate technology, is a ratio of two incremental costs: the cost per pound to upgrade a POTW from secondary treatment to advanced secondary treatment is divided by the cost per pound to initially achieve secondary treatment from raw wasteload. If the industry ratio is lower than the benchmark, the candidate technology passes the industry cost test. The benchmark for industries whose ratio is based on long-term performance data is 1.29. The second tier benchmark for industries whose ratio is not based on long-term performance data is 0.68.

In calculating this ratio, EPA will consider any BCT cost per pound less than \$0.01 to be the equivalent of *de*

minimis or zero costs. There are cases in today's rulemaking where the numerator of the industry cost ratio and therefore the entire ratio are taken to be zero. EPA believes any *de minimis* cost per pound for a candidate BCT technology meets Congressional intent concerning the concept of reasonableness for purposes of the second test.

4. BCT Determination

EPA will evaluate both the POTW test and the industry cost-effectiveness test as measures of reasonableness. The most stringent technology option that "passes" these tests provides the basis for setting BCT effluent limitations. Generally, if all candidate technologies fail any of the tests, or if no candidate technologies more stringent than BPT are identified, then BCT effluent limitations are established at a level equal to BPT effluent limitations.

There may be instances where, because of a lack of comparable industry data, a strict comparison to the benchmarks developed in this rulemaking would undermine Congressional intent on cost-reasonableness. In such instances, EPA will develop appropriate procedures to evaluate cost-reasonableness on an industry-specific basis. Additionally, section 304(b)(4)(B) instructs the Agency to consider "other factors deemed appropriate" when making determinations about BCT. Again, EPA will support such evaluations on an industry-specific basis.

B. Industrial Categories Affected and Summary of Their Results

This final regulation identifies the methodology EPA uses to establish BCT effluent limitations, pursuant to the provisions of section 304(b)(4)(B) of the Clean Water Act. This methodology is used in today's rulemaking to establish BCT effluent limitations for many of the secondary industries. For some of the primary industries, BCT effluent limitations have already been proposed; for others, they have been deferred. While BCT effluent limitations for primary industries will be promulgated in separate rulemaking notices, the methodology used to determine the reasonableness of those limitations will be the same as described in today's final rule.

Due to the extensive regulatory activity (proposal, promulgation, withdrawal, and reproposal) and the time span affecting BCT effluent limitations for the secondary industries, all subcategories for the secondary industries are reviewed here. Table 1 summarizes the results of this review.

The third column of Table 1 describes the status of BCT effluent limitations prior to today's rulemaking. The fourth column indicates whether the existing status is affected by this rulemaking and shows the final outcome. The final column presents the rationale for the final determination.

The results indicate that establishing BCT effluent limitations at a level of control more stringent than BPT effluent

limitations is reasonable for seven subcategories. Four subcategories are in the Canned and Preserved Seafood Processing category: Pacific Coast Hand-Shucked Oyster, Atlantic and Gulf Coast Hand-Shucked Oyster, Non-Alaskan Scallop, and Abalone Processing; two are in the Meat Products category: Small Processors and Renderers; and one is in the Phosphate Manufacturing category: Sodium

Phosphates. The Agency estimates that the additional treatment associated with the more stringent limitations for these subcategories will result in minimal incremental costs. For the remaining subcategories where BCT effluent limitations are established equal to the BPT effluent limitations, there is no incremental cost beyond BPT.

TABLE 1.—SUMMARY OF BCT METHODOLOGY RESULTS AND BCT EFFLUENT LIMITATIONS GUIDELINES FOR SECONDARY INDUSTRIES

Industry and subpart	CFR part	Prior status of BCT effluent limitations	Outcome of today's rulemaking	Basis of determination ¹
DAIRY PRODUCTS PROCESSING				
A—Receiving stations	405.17	No limitations	Establish BCT=BPT for BOD, TSS, pH	Fail BCT methodology, reason No. 3.
B—Fluid products	405.27	do	do	Do.
C—Cultured products	405.37	do	do	Do.
D—Butter	405.47	do	do	Do.
E—Cottage cheese and cultured cream cheese	405.57	do	do	Do.
F—Natural and processed cheese	405.67	do	do	Do.
G—Fluid mix for ice cream and other frozen desserts	405.77	do	do	Do.
H—Ice cream, frozen desserts, novelties and other dairy desserts	405.87	do	do	Do.
I—Condensed milk	405.97	do	do	Do.
J—Dry milk	405.107	do	do	Do.
K—Condensed whey	405.117	BCT=BPT for pH	No change for pH. Establish BCT=BPT for BOD, TSS.	Do.
L—Dry whey	405.127	No limitations	Establish BCT=BPT for BOD, TSS, pH	Do.
GRAIN MILLS				
A—Corn wet milling	406.17	Limitations suspended	No change to prior status	Technology under review.
B—Corn dry milling	406.27	No limitations	Establish BCT=BPT for BOD, TSS, pH	Fail BCT methodology, reason No. 3.
C—Normal wheat flour milling	406.37	BCT=BPT, zero discharge	No change to prior status	No candidate technology.
D—Bulgar wheat flour milling	406.47	BCT=BPT for pH	No change for pH. Establish BCT=BPT for BOD, TSS.	Fail BCT methodology, reason No. 3.
E—Normal rice milling	406.57	BCT=BPT, zero discharge	No change to prior status	No candidate technology.
F—Parboiled rice processing	406.67	No limitations	Establish BCT=BPT for BOD, TSS, pH	Fail BCT methodology, reason No. 3.
G—Animal feed	406.77	BCT=BPT, zero discharge	No change to prior status	No candidate technology.
H—Hot cereal	406.87	do	do	Do.
I—Ready-to-eat cereal	406.97	No limitations	Establish BCT=BPT for BOD, TSS, pH	Fail BCT methodology, reason No. 3.
J—Wheat starch and gluten	406.107	do	do	Do.
CANNED AND PRESERVED FRUITS AND VEGETABLES PROCESSING				
A—Apple juice	407.17	BCT=BPT for pH	No change for pH. Establish BCT=BPT for BOD, TSS.	Do.
B—Apple products	407.27	do	do	Do.
C—Citrus products	407.37	No limitations	Establish BCT=BPT for BOD, TSS, pH	Do.
D—Frozen potato products	407.47	BCT=BPT for pH	No change for pH. Establish BCT=BPT for BOD, TSS.	Do.
E—Dehydrated potato products	407.57	No limitations	Establish BCT=BPT for BOD, TSS, pH	Do.
F—Canned and preserved fruits	407.67	do	do	Do.
G—Canned and preserved vegetables	407.77	do	do	Do.
H—Canned and miscellaneous specialties	407.87	do	do	Do.
CANNED AND PRESERVED SEAFOOD PROCESSING				
A—Farm-raised catfish processing	408.17	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
B—Conventional blue crab processing	408.27	do	do	Fail BCT methodology, reason No. 1.
C—Mechanized blue crab processing	408.37	do	do	Do.
D—Non-remote Alaskan crab meat processing	408.47	do	do	Do.
E—Remote Alaskan crab meat processing	408.57	do	Establish BCT=BPT	Do.
F—Non-remote Alaskan whole crab and crab section processing	408.67	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
G—Remote Alaskan whole crab and crab section processing	408.77	do	Establish BCT=BPT	Do.
H—Dungeness and Tanner crab processing in the contiguous States	408.87	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
I—Non-remote Alaskan shrimp processing	408.97	do	do	Do.
J—Remote Alaskan shrimp processing	408.107	do	Establish BCT=BPT	Do.
K—Northern shrimp processing in the contiguous States	408.117	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
L—Southern non-breaded shrimp processing in the contiguous States	408.127	do	do	Do.
M—Breaded shrimp processing in the contiguous States	408.137	do	do	Do.
N—Tuna processing	408.147	do	do	Do.
O—Fish meal processing	408.157	do	Establish BCT=BPT for BOD, TSS, oil and grease, pH.	Fail BCT methodology, reason No. 2.
P—Alaskan hand-butchered salmon processing	408.167	do	Reserve section	Technology under review.
—Non-remote	do	do	Establish BCT=BPT	Fail BCT methodology, reason No. 1.
—Remote	do	do	do	Do.
Q—Alaskan mechanized salmon processing	408.177	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
—Non-remote	do	do	do	Do.

TABLE 1.—SUMMARY OF BCT METHODOLOGY RESULTS AND BCT EFFLUENT LIMITATIONS GUIDELINES FOR SECONDARY INDUSTRIES—Continued

Industry and subpart	CFR part	Prior status of BCT effluent limitations	Outcome of today's rulemaking	Basis of determination ¹
—Remote		do	Establish BAT = BPT.	Do.
R—West coast hand-butchered salmon processing	408.187	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
S—West coast mechanized salmon processing	408.197	do	do	Do.
T—Alaskan bottom fish processing	408.207			
—Non-remote		do	Reserve section.	Technology under review.
—Remote		do	Establish BCT=BPT.	Fail BCT methodology, reason No. 1.
U—Non-Alaskan conventional bottom fish processing	408.217	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
V—Non-Alaskan mechanized bottom fish processing	408.227	do	do	Do.
W—Hand-shucked clam processing	408.237	do	do	Fail BCT methodology, reason No. 2.
X—Mechanized clam processing	408.247	do	do	Fail BCT methodology, reason No. 1.
Y—Pacific coast hand-shucked oyster processing	408.257	do	Establish BCT=BPT for pH and BCT more stringent than BPT for TSS, oil and grease.	Pass BCT methodology.
Z—Atlantic and Gulf Coast hand-shucked oyster processing	408.267	do	do	Do.
AA—Steamed and canned oyster processing	408.277	do	Establish BCT=BPT for TSS, oil and grease, pH.	Fail BCT methodology, reason No. 1.
AB—Sardine processing	408.287	do	do	Do.
AC—Alaskan scallop processing	408.297			
—Nonremote		do	Reserve section.	Technology under review.
—Remote		do	Establish BCT=BPT.	Fail BCT methodology, reason No. 1.
AD—Non-Alaskan scallop processing	408.307	do	Establish BCT=BPT for pH and BCT more stringent than BPT for TSS, oil and grease.	Pass BCT methodology.
AE—Alaskan herring fillet processing	408.317			
—Non-remote		do	Establish BCT=BPT for TSS, oil and grease, pH.	Fail BCT methodology, reason No. 1.
—Remote		do	Establish BCT=BPT.	Do.
AF—Non-Alaskan herring fillet processing	408.327	do	Establish BCT=BPT for TSS, oil and grease, pH.	Do.
AG—Abalone processing	408.337	do	Establish BCT=BPT for pH and BCT more stringent than BPT for TSS, oil and grease.	Pass BCT methodology.
SUGAR PROCESSING				
A—Beet sugar processing	409.17	BCT=BPT for pH	No change for pH. Establish BCT=BPT for BOD, TSS, fecal coliform.	Fail BCT methodology, reason No. 3.
B—Crystalline cane sugar refining	409.27	do	No change for pH. Establish BCT=BPT for BOD, TSS.	Do.
C—Liquid cane sugar refining	409.37	do	No change for pH. Establish BCT=BPT for BOD, TSS.	Do.
D—Louisiana raw cane sugar processing	409.47	No limitations	Establish BCT=BPT for BOD, TSS, pH	Do.
E—Florida and Texas raw cane sugar processing	409.57	do	Establish BCT=BPT	No candidate technology.
F—Hilo-Hamaku Coast of the Island of Hawaii raw cane sugar processing	409.67	do	Establish BCT=BPT for BOD, TSS, pH	Fail BCT methodology, reason No. 3.
G—Hawaiian raw cane sugar processing subcategory	409.77	do	Establish BCT=BPT	No candidate technology.
H—Puerto Rican raw cane sugar processing	409.87	do	Establish BCT=BPT for BOD, TSS, pH	Fail BCT methodology, reason No. 3.
CEMENT MANUFACTURING				
A—Nonleaching	411.17	BCT=BPT pH, TSS	No change to prior status.	No candidate technology.
B—Leaching	411.27	BCT=BPT for pH	No change for pH. Establish BCT=BPT for TSS.	Fail BCT methodology, reason No. 3.
C—Materials storage piles runoff	411.37	BCT=BPT for pH, TSS	No change to prior status.	No candidate technology.
FEEDLOTS				
A—All subcategories except ducks	412.17	BCT=BAT	Reserve section.	Technology under review.
B—Ducks	No section	No limitations	No change to prior status.	Do.
FERTILIZER MANUFACTURING				
A—Phosphate	418.17	BCT=BPT for TSS	do	No candidate technology. ²
B—Ammonia	418.27	BCT=BPT for pH	do	Do.
C—Urea	No section	No limitations	do	No control of conventional pollutant discharges.
D—Ammonium nitrate	do	do	do	Do.
E—Nitric acid	do	do	do	Do.
F—Ammonium sulfate production	418.67	BCT=BPT	do	No candidate technology.
G—Mixed and blended fertilizer production	418.77	do	do	Do.
PHOSPHATE MANUFACTURING				
A—Phosphorus production	No section	No limitations	do	No control of conventional pollutant discharges.
B—Phosphorus consuming	do	do	do	Do.
C—Phosphate	do	do	do	Do.
D—Defluorinated phosphate rock	422.47	BCT=BPT for TSS, pH	do	No candidate technology.
E—Defluorinated phosphoric acid	422.57	do	do	Do.

TABLE 1.—SUMMARY OF BCT METHODOLOGY RESULTS AND BCT EFFLUENT LIMITATIONS GUIDELINES FOR SECONDARY INDUSTRIES—Continued

Industry and subpart	CFR part	Prior status of BCT effluent limitations	Outcome of today's rulemaking	Basis of determination ¹
F—Sodium phosphates	422.67	No limitations	Establish BCT=BPT for pH and BCT more stringent than BPT for TSS.	Pass BCT methodology.
FERROALLOY MANUFACTURING				
A—Open electric furnaces with wet air pollution control devices	424.17	do	Establish BCT=BPT for TSS, pH	Fail BCT methodology, reason No. 3.
B—Covered electric furnaces and other smelting operations with wet air pollution control devices	424.27	do	do	Do.
C—Slag processing	424.37	do	do	Do.
D—Covered calcium carbide furnaces with wet air pollution control devices	424.47	BCT=BPT for pH	No change for pH. Establish BCT=BPT for TSS.	Do.
E—Other calcium carbide furnaces	424.57	BCT=BPT	No change to prior status	No candidate technology.
F—Electrolytic manganese products	424.67	BCT=BPT for pH	No change for pH. Establish BCT=BPT for TSS.	Fail BCT methodology, reason No. 3.
G—Electrolytic chromium	424.77	do	do	Do.
GLASS MANUFACTURING				
A—Insulation fiberglass	426.17	No limitations	Establish BCT=BPT for BOD, TSS, pH	Do.
B—Sheet glass manufacturing	426.27	BCT=BPT	No change to prior status	No candidate technology.
C—Rolled glass manufacturing	426.37	do	do	Do.
D—Plate glass manufacturing	426.47	No limitations	Establish BCT=BPT for TSS, pH	Fail BCT methodology, reason No. 3.
E—Float glass manufacturing	426.57	BCT=BPT for pH	No change for pH. Establish BCT=BPT for TSS, oil.	Do.
F—Automotive glass tempering	426.67	do	do	Do.
G—Automotive glass laminating	426.77	do	do	Do.
H—Glass container manufacturing	426.87	do	do	Do.
I—Machine pressed and blown glass manufacturing	No section	No limitations	No change to prior status	No control of conventional pollutant discharges.
J—Glass tubing (Danner) manufacturing	426.107	BCT=BPT for pH	No change for pH. Establish BCT=BPT for TSS.	Fail BCT methodology, reason No. 3.
K—Television picture tube envelope manufacturing	426.117	do	No change for pH. Establish BCT=BPT for TSS, oil.	Do.
L—Incandescent lamp envelope manufacturing	426.127	do	do	Do.
M—Hand pressed and blown glass manufacturing	426.137	BCT set for pH	Reserve section	Technology under review.
ASBESTOS MANUFACTURING				
A—Asbestos-cement pipe	No section	No limitations	No change to prior status	Do.
B—Asbestos-cement sheet	do	do	do	Do.
C—Asbestos paper (starch binder)	do	do	do	Do.
D—Asbestos paper (elastomeric binder)	do	do	do	Do.
E—Asbestos millboard	do	do	do	Do.
F—Asbestos roofing	do	do	do	Do.
G—Asbestos floor tile	do	do	do	Do.
H—Coating or finishing of asbestos textiles	do	do	do	Do.
I—Solvent recovery	427.97	BCT=BCT for TSS, pH	do	No candidate technology.
J—Vapor absorption	No section	No limitations	do	Technology under review.
K—Wet dust collection	do	do	do	Do.
MEAT PRODUCTS				
A—Simple slaughterhouse	432.17	BCT=BPT for fecal coliform, pH in some processes	Establish BCT=BPT for BOD, TSS, oil and grease, fecal coliform, pH as limited in each process.	Fail BCT methodology, reason No. 1.
B—Complex slaughterhouse	432.27	do	do	Do.
C—Low-processing packinghouse	432.37	do	do	Do.
D—High-processing packinghouse	432.47	do	do	Do.
E—Small processor	432.57	No limitations	Establish BCT more stringent than BPT for BOD, TSS, oil and grease, pH, fecal coliforms.	Pass BCT methodology.
F—Meat cutter	432.67	BCT=BPT for fecal coliform, pH	No change for fecal coliform, pH. Establish BCT=BPT for BOD, TSS, oil and grease.	Fail BCT methodology, reason No. 1.
G—Sausage and luncheon meats processor	432.77	do	do	Do.
H—Ham processor	432.87	do	do	Do.
I—Canned meats processor	432.97	do	do	Do.
J—Renderers	432.107	No limitations	Establish BCT more stringent than BPT for BOD, TSS, oil and grease, pH, fecal coliform.	Pass BCT methodology.

¹ Further Explanation of Table Entries for "Basis for Determination."

Fail BCT methodology, reason No. 1: EPA has not identified a technically feasible candidate technology more stringent than BPT.

Fail BCT methodology, reason No. 2: EPA has not identified an economically achievable candidate technology more stringent than BPT.

Fail BCT methodology, reason No. 3: The candidate technology is not cost-reasonable; it fails the BCT cost test.

No control of conventional pollutant discharges: EPA has not yet identified a need to control conventional pollutant discharges in this subcategory. For some subcategories, there are no regulations currently in effect.

No candidate technology: EPA has not identified a candidate technology providing more stringent control of conventional pollutants than BPT. This applies to subcategories where BPT and BCT require zero discharge.

Technology under review: The BCT candidate technology is still being reviewed as a basis for setting BCT effluent limitations. The review may pertain to technical feasibility, economic achievability, or cost-reasonableness.

² For the Phosphate Fertilizer subcategory, the Agency has proposed an amendment to the applicability section that would exclude four plants in Louisiana from BAT and BCT effluent limitations guidelines. Final action on the amendment is pending. As part of that rulemaking, EPA will consider appropriate BCT effluent limitations guidelines for facilities in Louisiana.

III. Development of BCT Methodology and Benchmarks

A. POTW Test

As discussed earlier in this preamble, the 1979 BCT promulgation addressed the concept of reasonableness with a single measure that would be applied to BCT determinations in all industries. The Agency determined that a single methodology, or "rule-of-thumb" approach was preferable to a case-by-case approach. The core of the 1979 methodology, as directed by the statute, was a comparison of the cost of removing additional pounds of conventional pollutants by industrial dischargers to the cost of conventional pollutant removals by a POTW.

EPA considered a number of ways that a POTW test could be formulated (see the preamble to the proposed rules at 43 FR 35572, August 23, 1978). By 1977, industry was required to control pollutant discharges at a level achievable by BPT. Analogously, POTWs were required to have met effluent limitations based on secondary treatment by 1977. The Agency believed that a relevant basis of comparison for POTWs would be at an incremental level beyond secondary treatment because BCT effluent limitations guidelines would be at least equal to, and in some cases, more stringent than BPT effluent limitations guidelines. After a careful consideration of alternatives, EPA adopted a test employing a comparison of the cost to upgrade POTWs from secondary treatment to advanced secondary treatment.

Some commenters have argued that the repeal of Section 301(b)(2)(B) of the Clean Water Act changed EPA's statutory authority for relying on cost to upgrade to advanced secondary treatment as a basis for the BCT methodology. Section 301(b)(2)(B) had required that POTWs achieve "best practicable wastewater treatment technology" (BPWTT) by July 1, 1983. We do not believe that the repeal of BPWTT diminishes the rationale for using advanced secondary treatment in the POTW test or in the industry cost test.

In its final regulation on August 29, 1979, EPA stated three major reasons for using advanced secondary treatment in the POTW test (44 FR 50735). The first

was that "calculation of the costs per pound of conventional pollutant removal based on the increment from secondary to advanced secondary yields the best approximation of . . . marginal costs." The second was that advanced secondary treatment represents the "knee-of-the-curve" with respect to POTW costs (referring to the point where incremental costs begin to exceed incremental benefits). The last reason was that the level of treatment for a POTW to upgrade from secondary to advanced secondary treatment roughly parallels the industrial increment under consideration. In its review, the Fourth Circuit upheld EPA's choice of advanced secondary treatment as the relevant increment for the POTW benchmark. These reasons remain the basis for our choice of the secondary to advanced secondary increment as the foundation of the POTW test.

B. Industry Cost Test

The methodology promulgated in 1979 included only the POTW test. The methodological changes proposed in 1982 were primarily in response to the 1981 Court decision, which directed EPA to develop a second test to compare the industry cost and effluent reduction benefits resulting from more stringent levels of conventional pollutant control. Neither the Court nor the legislative history of the Clean Water Act provide specific guidance on how to design this second test. In developing the industry cost-effectiveness test (or "industry cost test"), the Agency determined that it should be designed so as to meet three conditions. First, the industry cost test should use an explicit numerical benchmark. By comparing industry costs to a uniform benchmark, EPA reduces bias in evaluating so many different industries. Second, the test should measure both increases in pollution control costs and reductions of conventional pollutants and thus measure the cost-effectiveness (in cost per pound removed) of the potential BCT level of control. Third, the test should be designed so that, from a practical standpoint, the information needed to conduct the test is generally available and promulgation of BCT effluent limitations guidelines would not be further delayed.

The Agency considered several alternative structures for the second test. The 1982 notice of proposed rulemaking discussed five ways to measure industry cost-effectiveness and two ways to establish the benchmark against which the industry values would be compared. The alternatives and the rationale for selecting an alternative are discussed in detail in the preamble to the proposed rule (47 FR 49181). The industry cost and pollutant removal calculations were based on an "increasing cost ratio" that combined two computations of cost per pound removed—one to reflect the control afforded by BPT effluent limitations and the second to reflect the additional control afforded by the candidate BCT technology. While the calculations for the second test have been refined in response to comments, the second test used in today's final regulation is conceptually the same as that proposed in 1982.

One of the refinements corrected an inconsistency in the "starting point" for calculating the cost per pound for secondary treatment and the cost per pound for BPT. In the 1982 proposal, some calculations of effluent reduction were based on raw waste pollutant concentrations; in other cases, primary treatment concentrations were used. Instead of using various levels of treatment for pre-BPT (or pre-secondary) conditions, the Agency established raw wasteload as the starting point both for industrial calculations and for POTW calculations (i.e., the pre-BPT and pre-secondary treatment levels). These changes address the concerns of commenters and maintain consistency between POTW and industry calculations. Additionally, where the cost per pound for a BCT candidate technology is less than \$0.01, EPA will consider the numerator of the industry cost ratio and, therefore, the entire ratio to be zero (see Section II.A.3).

C. POTW Cost Data

1. History and Overall Approach to POTW Cost Data

The methodology for both tests relies on the cost for POTWs to control conventional pollutants. The source of POTW cost data was a controversial

issue during several of the previous BCT rulemaking actions. In the 1979 promulgation and in the 1982 reproposal, EPA relied on empirical cost data. However, the 1982 action incorporated two revisions concerning EPA's use of the empirical data base. First, in the 1979 promulgation, the POTW cost comparison figure (the "POTW benchmark") was based on costs and removals for an average-sized POTW, which was 2 million gallons per day (mgd). In 1982, EPA proposed to base the POTW benchmark on cost and removal data for a range of POTW sizes. Costs per pound of pollutant removed were calculated for each of the various sizes, and then the costs were flow-weighted and summed to obtain a single POTW benchmark. The use of data for different POTW flow sizes better depicts the costs of removing conventional pollutants at POTWs because the economies of scale inherent in large POTWs can be included in the calculations. The flow-weighting approach is retained in the final rule.

Second, the 1982 proposal incorporated corrected and updated POTW cost data to calculate the POTW benchmark and the new industry cost benchmark. Incremental annual costs in the 1979 promulgation were estimated from actual POTW cost data collected by the Agency and reported in two cost documents (EPA 430/9-77-013, January 1978 and EPA 430/9-77-015, May 1978). The source of the actual cost data used in the 1982 proposal was the updated version of the cost documents used in 1979 (for the 1982 notice: EPA 430/9-80-003, April 1980 and EPA 430/9-81-004, September 1981). In both rulemakings, the cost documents provided the most up-to-date information regarding the costs of constructing and operating POTWs.

In 1983, more up-to-date cost information was again available, and on June 2, 1983, the Agency issued a notice indicating EPA's intent to use the most current data to promulgate the BCT methodology. EPA then became aware that the new data might not be appropriate for estimating the incremental cost of advanced secondary treatment. In the analysis of construction cost data, it appeared that the editing criteria to define secondary treatment systems and advanced secondary treatment systems might have been inaccurate or inconsistent. POTW costs may also have varied substantially due to site-specific factors that were unrelated to treatment plant performance. The empirical data base was not an actual study of upgrade costs at specific plants, which hindered

the Agency's attempt to calculate an incremental cost. In September 1983, the Agency withdrew the new data to further evaluate the costs. The Agency also realized that the cost curves used in the 1982 proposal might be subject to the same problems as the cost curves published and withdrawn in 1983. EPA then concluded that it was necessary to use a different data source to calculate incremental costs for the POTW and industry cost benchmarks.

The alternative approach was to develop model POTWs with specified design assumptions and then present design cost estimates for those models to determine the cost of upgrading POTWs from secondary treatment to advanced secondary treatment.

The model POTWs are municipal wastewater treatment facilities with specifications for size, basic design, general operating conditions, and required effluent levels. These specifications were provided to four engineering consulting firms who then estimated the model POTW costs. The design criteria for secondary treatment required that the POTW achieve effluent limitations of 30 milligrams per liter (mg/l) BOD and 30 mg/l TSS (as maximums for 30-day averages), using technology that was current in 1977. While in some circumstances, a permit authority may allow less stringent effluent limitations for certain POTWs (e.g., 45 mg/l BOD and 45 mg/l TSS for a POTW with a trickling filter), effluent limitations of 30 mg/l BOD and 30 mg/l TSS were used for the model POTWs because, unless adjusted, they are required by the Agency's secondary treatment regulation (40 CFR 133.105).

The design criteria for advanced secondary treatment required that the secondary treatment POTW be modified to achieve more stringent effluent levels. In the 1984 notice, the Agency identified three possible effluent levels for defining advanced secondary treatment: 20 mg/l for BOD and TSS, 15 mg/l, and 10 mg/l. For each level, the Agency specified a treatment technology that could be used to upgrade the secondary POTW to meet the more stringent effluent limitations. Of the three effluent levels, the Agency selected 20 mg/l BOD and 20 mg/l TSS (as maximums for monthly averages) as the most appropriate definition of advanced secondary treatment.

In the 1982 proposal, the increment to advanced secondary treatment was from 30 mg/l to 10 mg/l for both pollutants. The Agency used a definition of 10 mg/l each of BOD and TSS in that proposal because it represented the best performance for advanced secondary treatment. In the 1984 notice, the Agency

identified 20 mg/l BOD as a better choice because it was the most common permit requirement for POTWs beyond secondary treatment. Overall, the comments received on the definition of 20 mg/l were favorable, and the Agency is retaining this definition in the final methodology.

The model POTW approach was presented in the 1984 notice of data availability. Many comments supported the change to the design estimates, but the Agency received some detailed criticism of some of the design assumptions. Based on those comments, the final methodology includes some changes that refine and improve the data used for the benchmark calculations. These refinements are discussed below. The Agency is aware of the difficulties with both the empirical data base and the design estimates (see section IX, Comment Nos. 4, 8, and 9). On balance, and given the several changes to the cost data, we have determined that using design estimates is the preferred approach, and have retained this approach in the final rule.

2. Design Specifications for Model Plants

The major change affecting the model POTW costs since the 1984 notice is the specification of polymer addition as the treatment needed to upgrade a secondary POTW to advanced secondary treatment. The original model POTW specifications in the 1984 notice identified the additional treatment only as chemical addition. One of the engineering firms that estimated model POTW costs chose alum for the additive; the others chose polymer. Based on the evaluation of the comments concerning the use of alum, the Agency decided to specify polymer addition as the technology for advanced secondary treatment. While alum is effective at reducing the level of solids, its addition is usually associated with site-specific problems such as a high phosphorus content in the wastewater. The addition of polymer is a better design assumption for model POTWs. This specification change precludes the use of alum, and the engineering firm that had initially used alum revised their design and costs to reflect polymer addition.

The technology basis for secondary treatment for the model POTW is conventional activated sludge. Various sludge disposal methods are used, depending on the size of the model POTW. As mentioned above, polymer addition is the technology to upgrade the secondary POTW to meet effluent limitations of 20 mg/l BOD and 20 mg/l

TSS. Some secondary POTWs with conventional activated sludge processes may achieve better performance than 30 mg/l BOD and 30 mg/l TSS and may intermittently achieve 20 mg/l BOD and 20 mg/l TSS without additional technologies. With the constraint that an existing POTW is being modified, however, consistent and reliable performance at more stringent levels can best be achieved with additional treatment and, therefore, additional cost. Some of the comments on the 1984 notice claim that activated sludge POTWs will routinely meet the Agency's defined level of advanced secondary treatment without additional technology; that is, through better operation of existing facilities. These claims were supported by performance data from certain POTWs.

Considering the characteristics of POTWs as a whole, the Agency believes this claim is an overstatement of a secondary POTW's capability. The polymer addition step, however, would ensure that the defined level of advanced secondary treatment will be met. Polymers have been used to improve the performance of secondary POTWs; the technology is not prohibitively expensive, and it is well documented as effective. Commenters also challenged a series of specific model POTW design and costing assumptions. Many of their comments addressed sizing and capacity assumptions for specific equipment, such as influent pumps or vacuum filters. Agency engineers and each engineering firm evaluated each of these comments, reviewed the design assumptions and costs, and where necessary, corrected or revised the designs and costs.

3. Model POTW Cost Estimates

The procedure for using the engineering cost estimates is basically the same as presented in the 1984 notice. Estimates of the incremental cost to upgrade from secondary treatment to advanced secondary treatment were developed for five sizes of POTWs. Table 2 presents a distribution, by size, of POTWs in the United States. Each of the five model POTW sizes is approximately equal to the average flow in each size category, expressed in million gallons per day (mgd). The five model POTW sizes are 0.052 mgd, 0.38 mgd, 3.3 mgd, 25 mgd, and 140 mgd. The POTW and industry cost benchmarks continue to be based on weighting the cost per pound of conventional pollutants removed, according to the size distribution of POTWs. The weighting factors, shown on the last line of Table 2, are calculated by dividing

the total flow for each size category by the total flow for all POTWs.

As in the proposal, the POTW costs used to calculate the benchmarks are the total annual costs of constructing and operating a secondary POTW, and the total annual cost to upgrade the POTW to advanced secondary treatment. Total annual costs include capital charges, interest, and operation and maintenance costs. Capital costs are amortized over 30 years at a 10 percent interest rate. The engineering cost estimates are presented in 1984 dollars and then indexed to 1976 third quarter dollars and to other years' dollars to facilitate comparison of the benchmark to the costs of BCT candidate technologies for industrial subcategories.

The engineering firms that provided model POTW estimates and the model POTW sizes analyzed by the respective firms are the same as those presented in the 1984 notice. The four firms are Camp Dresser and McKee, Inc., E. C. Jordan Co., Sverdrup and Parcel and Associates, Inc., and J. M. Smith and

Associates Consulting Engineers. Each firm is nationally recognized for experience in designing municipal wastewater treatment facilities. The first three firms estimated costs for the three largest model POTW sizes: 3.3, 25, and 140 mgd. For these model POTWs, the three firms developed detailed estimates based on preliminary design of POTW components. The fourth firm, using planning level estimates, provided costs for the two smaller POTW sizes: 0.052 and 0.38 mgd. Planning level cost estimates were developed from empirically-based, cost-estimating curves that present costs as a function of size and also with a computer-assisted, cost-estimating program (the EPA-developed CAPDET: Computer Assisted Procedure for the Design and Evaluation of Wastewater Treatment Systems). Planning level estimates usually have a lower degree of accuracy than design estimates. However, this does not significantly affect the benchmarks because the weighting factors for the two smallest POTW sizes are very low (see Table 2).

TABLE 2—POTW SIZE DISTRIBUTION

	Size Range by Flow (mgd) ¹					
	0 to 0.105	0.106 to 1.05	1.06 to 10.5	10.6 to 50.2	50.3 & greater	All POTWs
Number of POTWs.....	5,021	7,033	2,686	415	96	15,251
Total flow.....	259	2,675	8,836	9,290	13,354	34,415
Average flow.....	0.0515	0.3803	3.290	22.39	139.1	2.257
Weighting factor.....	.0075	.0777	.2567	.2700	.3890	1.0

¹ mgd = millions of gallons per day.

Source: The 1980 Needs Survey (FRD-23; EPA 430/9-81-008, February 1981).

Each engineering firm estimated costs for a secondary POTW and for the upgrade of the POTW to advanced secondary treatment. A summary of the cost estimates is shown in Table 3. Each firm reported their estimates on a standard format to facilitate review and comparison. The reporting format presents the costs for 18 cost centers (e.g., primary clarification, aeration, chlorination) and for 16 cost divisions (e.g., electrical, concrete, equipment) within each cost center. A review of the cost estimates highlighted the major areas of difference among the firms, and also identified areas needing further review. After reviewing the final cost estimates submitted by the engineering firms, the Agency concluded that the differences in cost estimates are attributable to differences in engineering philosophies. While the basic design criteria and general operating conditions were the same for all three firms, the specific design criteria were determined by each firm, according to their best judgment, experience, and expertise. Comparisons of individual cost centers show that differences exist in the choice

of equipment, size and operating specifications of equipment, structures that house the components, POTW layout, and labor requirements.

TABLE 3.—POTW TOTAL ANNUAL COST ESTIMATES FOR SECONDARY TREATMENT AND THE INCREMENTAL COST FOR ADVANCED SECONDARY TREATMENT

[1984 dollars, in millions]					
	Size of Model POTW (mgd)				
	0.052	0.38	3.3	25	140
Total annual costs for secondary treatment:					
JMS.....	0.07	0.27			
CDM.....			3.23	11.81	42.36
ECJ.....			1.99	8.39	29.63
S&P.....			1.79	8.16	32.99
Incremental cost for advanced secondary treatment:					
JMS.....	0.0	0.0			
CDM.....			0.07	0.45	1.86
ECJ.....			0.11	0.44	1.28
S&P.....			0.07	0.34	1.53

Key:

JMS: J.M. Smith and Associates Consulting Engineers.
CDM: Camp Dresser and McKee, Inc.
ECJ: E.C. Jordan Co.
S&P: Sverdrup and Parcel and Associates, Inc.

For both secondary and advanced secondary POTWs, the Agency believes that the cost estimates prepared by the engineering firms are representative of the costs to construct and operate a POTW at the specified treatment level. Therefore, all of those estimates were used in the benchmark calculations. For the three largest POTW sizes where there are three estimates, mean costs (arithmetic averages) were calculated for each model POTW size. These average costs, after indexing to 1976 third quarter dollars, are shown in Table 4.

TABLE 4.—TOTAL ANNUAL COSTS FOR MODEL PLANTS
[1976 dollars, in millions]

	Size of POTW (mgd)				
	0.052	0.38	3.3	25	140
Total annual cost for secondary treatment.....	0.040	0.156	1.351	5.456	20.151
Total annual cost of increment to advanced secondary treatment.....	0	0	0.047	0.240	0.883

D. POTW Performance Data

1. Use of Long-Term Performance Data

Just as the calculations for both tests rely on the cost for POTWs to control conventional pollutants, the calculations also use the pounds of pollutants removed by various treatment technologies. Prior to the 1984 notice (i.e., in the 1982 proposal), the methodology was sometimes inconsistent in defining performance when comparing different levels of treatment (e.g., raw waste vs. secondary treatment) and when comparing POTW calculations to industry calculations. In some cases, long-term performance data were used; in other cases, maximum 30-day averages were used. For example, an industry's cost per pound, based on long-term data, was compared to a benchmark based on 30-day data. Inconsistent comparisons of this kind biased the test outcomes against industry. This problem was identified in comments on the 1982 proposal, and in the 1984 notice, the Agency responded with its planned corrections: (1) Whenever possible, use long-term performance data to calculate pounds of pollutants removed (where long-term performance is represented by a minimum of 12 months performance); and (2) compare industry costs of removal to POTW costs of removal on a consistent basis.

While the preferred approach for

calculating the pounds of pollutants removed is to base the calculations on long-term performance, the Agency lacks sufficient information to estimate long-term performance for the secondary industries for which BCT effluent limitations are established by this rulemaking. Instead, the pollutant removal calculations are based on maximum 30-day effluent limitations. To apply the methodology consistently, the Agency established a second tier of benchmarks, which are correspondingly based on maximum 30-day effluent limitations. Thus, the bias from inconsistent comparisons of treatment effectiveness is eliminated. A summary of the type of performance data used for each tier of calculations is shown in Table 5.

TABLE 5.—THE "TWO-TIER" APPROACH: TYPE OF PERFORMANCE DATA USED TO CALCULATE INCREMENTAL POLLUTANT REMOVALS

	Tier 1— Long-term effluent data available	Tier 2— Long-term effluent data not available
Industry Calculations:		
BPT.....	Long-term average.	Maximum 30-day average. Do.
BCT.....	do.....	Do.
Benchmark Calculations:		
Secondary Treatment.....	do.....	Do.
Advanced Secondary Treatment.....	do.....	Do.

While secondary treatment and advanced secondary treatment are generally defined by permit requirements (maximum 30-day limitations), the calculations for pounds of pollutant removed are based on long-term performance. EPA used actual long-term performance data for POTWs achieving the specified permit requirements (30 mg/l for secondary treatment and 20 mg/l for advanced secondary treatment) to derive long-term concentrations. The accuracy of long-term performance data is not greatly affected by site-specific factors and, thus it is appropriate for the Agency to use actual POTW performance data. The 1984 notice set forth the Agency's plans to derive long-term average pollutant concentrations that could be used in the BCT methodology by applying a set of editing criteria to a POTW performance data base to identify a group of POTWs representative of secondary and advanced secondary treatment.

The Agency received substantial comment on the POTW performance data that were used in the 1984 notice. Some comments were particularly critical of the editing criteria used to

identify secondary and advanced secondary POTWs in EPA's POTW performance data base. Comments on the 1984 notice generally supported the use of long-term average concentrations, but concern focused on the effluent concentrations that were used. Commenters claimed the long-term concentrations were not representative of secondary and advanced secondary POTWs.

The final methodology continues to use annual average concentrations and continues to derive them from actual performance data. The source of the performance data is a data base covering a range of POTW sizes and treatment technologies. The focus of the data collection effort (which was reported in EPA 430/9-81-004, September 1981) was POTW operation and maintenance costs, but the data base also contains performance data (such as influent and effluent pollutant concentrations), flow data, permit information, and the type of treatment at each facility. For purposes of the BCT methodology, secondary and advanced secondary POTWs are identified by editing the data base for well-operated POTWs that are characteristic of the specified treatment level in terms of permit requirements, performance, and treatment processes.

2. Editing Criteria for Long-Term Performance Data

a. *List of Editing Criteria.* The general objective of the performance data editing criteria is to identify POTWs characteristic of secondary and advanced secondary treatment. The current editing criteria are as follows. POTWs are excluded from the data base if any of the following criteria are met: (1) Less than 12 months of BOD and TSS effluent data are available. (2) Permit limit for the POTW is different than 30 mg/l BOD for a secondary POTW and 20 mg/l for an advanced secondary POTW. (3) BOD and TSS permit limits are exceeded more than once in a 12 month period. One exceedance is allowed for both BOD and TSS if occurring in the same month. (4) The POTW has unit processes not characteristic of either secondary treatment or advanced secondary treatment. The processes considered appropriate for secondary and advanced secondary POTWs are listed below. (5) All BOD and TSS concentrations are 20 mg/l or below for secondary treatment or 10 mg/l or below for advanced secondary treatment.

The first editing criterion remains unchanged from the 1984 notice and

simply defines EPA's minimum information requirements for POTWs in the data base. The second criterion reflects the definitions of secondary and advanced secondary treatment in terms of permit limitations. The three most significant changes from the 1984 notice concern the final three editing criteria.

b. *Criterion 3: Violation of BOD and TSS Permit Limits.* The original editing criteria (for the 1984 notice) to define secondary POTWs specified a permit limitation for BOD of 30 mg/l. The criteria also required that the POTW be in compliance with its permit; that is, the actual monthly average effluent levels for both BOD and TSS has to be 30 mg/l or lower. One violation was allowed, meaning that one monthly average effluent value for either BOD or TSS could exceed 30 mg/l. Some commenters claimed that allowing only one violation of the monthly average limit was inappropriate because the effluent TSS concentration is correlated to the effluent BOD concentration. As a result of this relationship, commenters claimed that the Agency had incorrectly eliminated POTWs from the analysis. To resolve this, EPA evaluated the relationship between BOD and TSS and concluded that, under certain conditions, allowing two violations is a more appropriate editing rule for defining a well-operated secondary POTW. Therefore, the final editing criteria allow one violation each of the BOD and TSS permit requirements if those violations occur in the same month. Violations in the same month only were permitted to allow for the relationship between BOD and TSS; this change is consistent with the objective of the editing criteria—to identify well-operated POTWs.

c. *Criterion 4: Uncharacteristic Unit Processes.* Another comment concerning the editing criteria was that under-performers (i.e., POTWs not in compliance with their permit requirements) were systematically excluded from the analysis while over-performers (i.e., POTWs operating such that BOD and TSS effluent concentrations were much lower than the permit requirements) were included. Commenters argued that including the over-performers lowers the overall average BOD and TSS effluent concentrations, resulting in an incorrect assessment of the performance of POTWs as a whole. The Agency evaluated these comments by analyzing the following factors that affect why POTWs might perform better than required by their permit: (1) Hydraulic loading, (2) unit processes, and (3) influent pollutant characteristics.

When a POTW is hydraulically underloaded (i.e., the daily volume of wastewater treated is less than the daily volume the POTW was designed to treat), performance may be better than the design performance. The issue of underloaded POTWs was raised repeatedly in the comments because many of the POTWs in the performance data base were underloaded. This issue was initially considered when the original editing criteria were established. The Agency evaluated the POTW data to determine if a relationship existed between the actual flow as a percent of design flow and effluent BOD and TSS concentrations. No statistically significant relationships were found.

Another reason why POTWs could perform better than required by their permits is that the unit processes at the POTW are not typical of secondary treatment. For example, a POTW may have a filter, which is more typical of advanced wastewater treatment than of secondary treatment, and still have secondary treatment permit limits (i.e., 30-day effluent BOD and TSS concentrations of 30 mg/l). In the initial editing criteria for calculating long-term averages, no consideration was given to the type of unit processes in a POTW. In response to comments, the Agency changed the editing rules so that unit processes would be considered in selecting POTWs whose effluent data would be used to calculate the long-term averages. Biological processes considered appropriate for secondary POTWs included trickling filter, rotating biological contactor, and activated sludge. These processes were selected because, when used with other processes such as settling units, they can achieve 30 mg/l BOD and 30 mg/l TSS and because, as reported in the 1978 EPA Needs Survey, they are the most prevalent biological treatment processes at POTWs. Unit processes considered appropriate for advanced secondary POTWs are those processes found in secondary POTWs plus chemical addition to the wastewater.

A third reason why POTW performance may vary concerns influent pollutant characteristics. If pollutant concentrations are high, the biological unit process may not become acclimated to the wastewater, and thus, not perform well. If the pollutant concentrations are low, there may not be enough organic material in the wastewater for the biological unit to operate properly. In either case, pollutant removals may be low. The Agency evaluated the impact of influent pollutant characterization on POTW performance by determining if a

statistical correlation exists between the influent and effluent pollutant concentrations. No significant correlation was found, suggesting that POTWs perform equally well within a broad range of influent wastewater pollutant concentrations.

Thus, based on the results of the Agency's review, the editing criteria were changed to reflect differences in unit processes. No changes were made based on either the POTW hydraulic loading or influent pollutant characteristics for the reasons discussed above.

d. *Criterion 5: Actual Performance Consistently Beyond Defined Treatment Levels.* Another criticism of the editing criteria presented in the 1984 notice was that actual performance of the POTWs was not considered, and as a consequence, the performance results were flawed. In the current editing criteria, the fifth criterion accounts for actual performance. The fifth criterion eliminates POTWs from the analysis if they consistently perform at levels better than would be characteristic of secondary or advanced secondary treatment. Two parameters were used to account for performance: (1) Effluent BOD and TSS concentrations and (2) the frequency of those effluent concentrations.

The fifth editing criterion for secondary treatment eliminates data for a POTW when all of a POTW's effluent BOD and TSS concentrations are 20 mg/l or below. The Agency selected 20 mg/l as the "cut-off" for secondary treatment because advanced secondary treatment is defined by maximum 30-day concentrations of 20 mg/l. Therefore, POTWs consistently meeting the requirements for advanced secondary treatment are excluded from the calculation of long-term averages for secondary treatment. For advanced secondary treatment, the fifth editing criterion eliminates a POTW from the data base when all of a POTW's effluent BOD and TSS concentrations are 10 mg/l or below. The 10 mg/l concentration is the effluent level at which the Agency believes the additional treatment needed to meet that concentration would be characterized as advanced wastewater treatment. The 20 mg/l "cut-off" for secondary treatment and the 10 mg/l "cut-off" for advanced secondary treatment were suggested by several commenters on the 1984 notice. The Agency agreed with the commenters and, therefore, adopted the fifth editing criterion.

The Agency believes that the final editing criteria yield a group of POTWs

characteristics of the specified treatment levels. POTWs whose permit limits, compliance records, treatment processes, and actual performance allowed them to remain in the performance data based were then used to calculate long-term average performance. Long-term BOD and TSS averages for each treatment level were calculated by averaging the monthly average BOD and TSS effluent concentrations for those POTWs identified as being representative of each treatment level.

3. Summary of POTW Performance Data

A summary of the performance data analysis is presented in Table 6. For secondary POTWs, the long-term average concentrations are 16.14 mg/l BOD and 15.84 mg/l TSS, based on data from 52 POTWs. For advanced secondary treatment, the long-term average concentrations are 10.24 mg/l BOD and 10.35 mg/l TSS, based on data from 22 POTWs. The change in average effluent concentrations from secondary to advanced secondary treatment is greater than the change presented in the September 1984 notice due to the revisions to the editing criteria. The Agency believes the effluent concentrations used in today's final regulation are characteristic of the specified treatment levels and are appropriate values to use to calculate the BCT benchmarks.

The number of pounds of pollutants removed at each treatment level is calculated by multiplying the change in concentration times the POTW flow (and multiplying by the appropriate conversion factors).

Using the concentrations for secondary and advanced secondary treatment shown in Table 6, the total change in effluent BOD and TSS concentration between secondary treatment and advanced secondary treatment is 11.39 mg/l. The number of pounds of pollutants removed for each of the flow sizes is shown in Table 7.

TABLE 6.—LONG-TERM AVERAGE EFFLUENT POTW CONCENTRATIONS

Treatment level	Number of POTWs in data base	Maximum 30-day average (mg/l)		Long-term average concentration (mg/l)	
		BOD	TSS	BOD	TSS
Raw waste				210	210
Secondary treatment.....	52	30.0	30.0	16.14	15.84
Advanced secondary treatment.....	22	20.0	20.0	10.24	10.35

TABLE 7.—INCREMENTAL POLLUTANT REMOVAL: SECONDARY TREATMENT TO ADVANCED SECONDARY TREATMENT

Flow (mgd)	Pollutants removed per year (million pounds of BOD and TSS)
0.052	0.002
0.38	0.013
3.3	0.114
25	0.867
140	4.857

E. Benchmark Calculations

1. The POTW Benchmark, First Tier

The first tier POTW benchmark is used for industry comparisons when long-term performance data are available—the preferred approach. The POTW benchmark is the incremental cost per pound to remove conventional pollutants beyond secondary treatment to advanced secondary treatment. The incremental cost is based on costs for five sizes of model POTWs, as described above, in Section C.3. The number of pounds of pollutant removed is based on the difference in long-term average pollutant concentrations between secondary and advanced secondary treatment, as described in Section D.

The next step in the calculations is to determine the incremental cost of removal. For each POTW flow, we divide the incremental annual cost (Table 4) by the incremental pollutant removal (Table 7) and weight the results by the factors shown in Table 2. These calculations are summarized in Table 8. The result is a benchmark of \$0.25 per pound (1976 dollars). The benchmark is indexed for other time periods in Table 9.

TABLE 8.—SUMMARY OF POTW BENCHMARK CALCULATIONS: SECONDARY TREATMENT TO ADVANCED SECONDARY TREATMENT, FIRST TIER

[1976 dollars]					
POTW flow (mgd)	Incremental annual cost (dollars million)	Incremental annual removal (million pounds)	Dollar per pound	Weighting factor	Weighted dollar per pound
0.052	0	0.002	0	0.0075	0
0.38	0	0.013	0	0.0777	0
3.3	0.047	0.114	0.41	0.2567	0.11
25	0.240	0.867	0.28	0.2700	0.07
140	0.863	4.857	0.18	0.3880	0.07
Total					0.25

TABLE 9.—POTW BENCHMARKS (FIRST TIER) FOR VARIOUS TIME PERIODS

Year	Quarter			
	1st	2nd	3rd	4th
1976	0.24	0.25	0.25	0.26
1978	0.28	0.29	0.29	0.30
1980	0.35	0.36	0.36	0.37
1982	0.42	0.42	0.43	0.43
1983	0.43	0.43	0.44	0.44
1984	0.44	0.45	0.45	0.46
1985	0.47	0.47	0.47	

2. The Industry Cost Benchmark, First Tier

The industry cost benchmark compares the POTW cost per pound of removing conventional pollutants between secondary treatment and advanced secondary treatment to the cost per pound removed between raw wastewater and secondary treatment. This section outlines the calculations for the industry cost test.

For each POTW flow category, we calculate the following ratio: incremental cost per pound for upgrading the POTW from secondary to advanced secondary treatment divided by the cost per pound to achieve secondary treatment from raw wastewater. The first value in the ratio is the same incremental cost per pound calculated for the first test (the POTW benchmark). The second value in the ratio is the cost per pound to achieve secondary treatment from raw wastewater. The costs to achieve secondary treatment, originally shown in Table 4, are repeated in Table 10. The incremental pollutant removals for raw wastewater to secondary treatment are calculated by multiplying the POTW flow by change in pollutant concentrations. The raw waste influent concentrations for the model POTWs are assumed to be 210 mg/l BOD and 210 mg/l TSS. These influent concentrations are annual averages based on the Agency's evaluation of POTW data from the "1980 Needs Survey" and from "Fate of Priority Pollutants in Publicly Owned Treatment Works" (EPA 440/1-82-303, September 1982). Thus, the change in concentration from raw waste to secondary treatment is from 210 to 16.14 mg/l for BOD and from 210 to 15.84 mg/l for TSS. The total change in concentration for both pollutants is 388.02 mg/l. This change in concentration is multiplied by flow to calculate the number of pounds removed by secondary treatment. These results are shown in the third column of Table 10. The dollar per pound values for each size category are then calculated by dividing the incremental cost by the

incremental removal. The results are shown in the final column of Table 10.

TABLE 10.—INCREMENTAL ANNUAL COST PER POUND OF POLLUTANTS REMOVED: RAW WASTE TO SECONDARY TREATMENT (FIRST TIER)

[1976 dollars]			
POTW flow (mgd)	Incremental annual cost (million dollars)	Incremental annual removal (million pounds)	Dollar per pound removed
0.052	0.040	0.061	0.66
0.38	0.156	0.449	0.35
3.3	1.351	3.900	0.35
25	5.456	29.545	0.18
140	20.151	165.451	0.12

The remaining industry cost benchmark calculations are summarized in Table 11. For each POTW flow, the cost per pound for the increment of secondary treatment to advanced secondary treatment is divided by the cost per pound for the increment of raw waste to secondary treatment. Those cost ratios are multiplied by the weighting factors for each size category, and the weighted ratios are summed to obtain the industry cost benchmark. The result of these calculations is a benchmark of 1.29.

TABLE 11.—SUMMARY OF INDUSTRY COST BENCHMARK CALCULATIONS (FIRST TIER)

POTW flow (mgd)	Incremental cost per pound (1976 dollars)		Cost ratio*	Weighting factor	Weighted ratio
	Raw waste to secondary treatment	Secondary treatment to advanced secondary			
0.052	0.66	0	0	0.0075	0
0.38	0.35	0	0	0.0777	0
3.3	0.35	0.41	1.20	0.2567	0.31
25	0.18	0.28	1.50	0.2700	0.40
140	0.12	0.18	1.49	0.3880	0.58
Total					1.29

* Interim result shown in this column may appear incorrect due to rounding.

3. Summary of Second Tier Benchmarks

a. Second Tier POTW Benchmark. Calculations for the second tier POTW benchmark are basically the same as the calculations for the first tier; the only differences are the pollutant concentrations used to calculate the pounds of pollutants removed. For the second tier, we use maximum 30-day average concentrations instead of long-term average concentrations. The calculations for the second tier POTW benchmark are summarized in Table 12. The incremental pollutant removals are

again calculated by multiplying the change in concentration by the POTW flow. For the second tier benchmark, the change in concentration is from 30 mg/l to 20 mg/l for both BOD and TSS. The resulting number of pounds of pollutants removed are shown in the third column of Table 12. For each POTW flow, the cost is then divided by the pollutant removal; the resulting dollar per pound is multiplied by the weighting factor; and the weighted costs are summed. The result of these calculations is a second tier POTW benchmark of \$0.14 per pound (1976 dollars).

TABLE 12.—SUMMARY OF SECOND TIER POTW BENCHMARK CALCULATIONS

[1976 dollars]					
POTW flow (mgd)	Incremental annual cost (million dollars)	Incremental annual removal (million pounds)	Dollar per pound	Weighting factor	Weighted dollar per pound
0.052	0	0.003	0	0.0075	0
0.38	0	0.023	0	0.0777	0
3.3	0.047	0.201	0.24	0.2567	0.06
25	0.240	1.523	0.16	0.2700	0.04
140	0.883	8.528	0.10	0.3880	0.04
Total					0.14

b. Second Tier Industry Cost

Benchmark. Calculations for the second tier industry benchmark are the same as the calculations for the first tier, with the exception of pollutant concentrations. The cost ratio remains as follows: the cost per pound to upgrade the POTW from secondary treatment to advanced secondary treatment is divided by the cost per pound to achieve secondary treatment from raw wasteload. The first value in the ratio has already been explained. For the second value in the ratio, the change in concentration for both BOD and TSS is from 210 mg/l to 30 mg/l. Thus, the total change in concentration is 360 mg/l, which is multiplied by flow to calculate the number of pounds removed by secondary treatment. The cost per pound for achieving secondary treatment from raw waste is shown in Table 13. The remaining benchmark calculations are summarized in Table 14. The cost ratios in the fourth column of Table 14 are multiplied by the weighting factors for each size category to obtain flow-weighted ratios. The sum of the flow-weighted ratios is the second tier industry cost benchmark of 0.68.

TABLE 13.—INCREMENTAL ANNUAL COST PER POUND OF REMOVAL FOR RAW WASTE TO SECONDARY TREATMENT (SECOND TIER)

[1976 dollars]			
POTW flow (mgd)	Incremental annual cost (dollars millions)	Incremental annual removal (million pounds)	Dollar per pound removed*
0.052	0.040	0.057	0.71
0.38	0.156	0.417	0.38
3.3	1.351	3.618	0.37
25	5.456	27.411	0.20
140	20.151	153.504	0.13

* Result shown in this column may appear incorrect due to rounding.

TABLE 14.—SUMMARY OF INDUSTRY COST BENCHMARK (SECOND TIER)

POTW flow (mgd)	Incremental cost per pound (1976 dollars)		Cost ratio*	Weighting factor	Weighted ratio
	Raw waste to secondary treatment	Secondary treatment to advanced secondary			
0.052	0.71	0	0	0.0075	0
0.38	0.38	0	0	0.0777	0
3.3	0.37	0.24	0.63	0.2567	0.16
25	0.20	0.16	0.79	0.2700	0.21
140	0.13	0.10	0.79	0.3880	0.31
Total					0.68

* Interim result shown in this column may appear incorrect due to rounding.

IV. Status of Proposed BCT Effluent Limitations Guidelines for Primary Industries

A. Introduction

The final methodology for determining cost reasonableness, as described in this preamble, generally applies to all industries. The rulemaking actions to promulgate or propose BCT effluent limitations for primary industries will appear in separate notices. The expected conclusions for two industries that have received special attention in previous BCT notices, Pharmaceutical Manufacturing and Pulp and Paper, are discussed below. For four other primary industries, the status of BCT effluent limitations is also presented because they were included in the 1982 proposal. Again, effluent limitations for these industries are not included in today's regulation, though today's rulemaking on the BCT methodology provides part of the basis for their subsequent promulgation.

B. Primary Industry Discussions

1. Pharmaceutical Manufacturing

EPA proposed BCT effluent limitations guidelines for the Pharmaceutical Manufacturing industry on November 26, 1982 (47 FR 53584). In a

Notice of Availability on March 9, 1984, EPA provided new cost information that would be used to develop BCT effluent limitations (49 FR 8967). In response to comments concerning that notice, the Agency revised the cost data and calculations used to conduct the BCT cost test. The revised cost data appear in the record for this rulemaking. While those revisions are preliminary and have not yet been published, based on the current data and analysis and the BCT methodology promulgated today, none of the BCT candidate technologies for the four subcategories would pass the cost test, and all four subcategories would have BCT effluent limitations equal to BPT effluent limitations. The Agency plans to promulgate final BCT limitations in a subsequent **Federal Register** notice.

2. Pulp, Paper, and Paperboard

BCT effluent limitations for the Pulp, Paper, and Paperboard industry were included in the 1982 BCT proposal (47 FR 49176). At that time, EPA proposed BCT effluent limitations more stringent than BPT effluent limitations for three subcategories (of a total of 25 subcategories). In 1984, when the Agency published possible changes to the methodology, the number of subcategories passing the BCT cost test increased to ten (49 FR 37046, September 20, 1984). Cost and effluent reduction data for the industry were still preliminary at that time, and the Agency indicated that revisions in those data were expected. These revisions are now nearly complete, and while not yet published, the Agency does not anticipate further changes regarding the impact of the BCT methodology. The revised data are included in the record for today's regulation. Based on the current analyses and the BCT methodology published today, the Agency expects that none of the BCT candidate technologies for any subcategory will pass the cost test, and that BCT effluent limitations for all subcategories will be established in a subsequent **Federal Register** notice as equal to BPT effluent limitations.

3. Timber Products

BCT effluent limitations were established for two of the 16 subcategories in January 1981 (46 FR 8285); they were subsequently withdrawn in February 1982 (47 FR 6835). In October 1982, EPA proposed BCT effluent limitations for 13 subcategories (47 FR 49176). The Agency is still evaluating the proposed limitations and plans to promulgate final limitations in a subsequent **Federal Register** notice.

4. Inorganic Chemicals

In the October 1982 BCT proposal (47 FR 49176), EPA proposed BCT effluent limitations for two subcategories, Hydrofluoric Acid and Chlor-Alkali (Diaphragm Cell). The Agency is still evaluating the proposed limitations and will promulgate final limitations in a subsequent **Federal Register** notice.

5. Metal Finishing

Effluent limitations based on BCT were included in the October 1982 BCT proposal (47 FR 49176). When most of the other effluent limitations guidelines were established for this category in July 1983 (e.g., those based on BPT and BAT, 48 FR 32485), EPA took no further action with respect to regulations based on BCT. The Agency is still evaluating the proposed BCT limitations and plans to promulgate final limitations in a subsequent **Federal Register** notice.

6. Ore Mining and Dressing

In the October 1982 BCT proposal, EPA proposed BCT effluent limitations for seven subcategories (47 FR 49176). When EPA issued the final regulation for this category in December 1982, all sections pertaining to BCT were reserved. The Agency is still evaluating the proposed limitations and plans to promulgate final limitations in a subsequent **Federal Register** notice.

In a subsequent action that only addressed the Gold Placer Mining Subcategory, EPA proposed BCT effluent limitations more stringent than BPT effluent limitations (50 FR 47982, November 20, 1985). As explained in the preamble to that proposed rule, the incremental cost per pound of removing conventional pollutants for the BCT candidate technology is minimal; the value is estimated to be less than one cent. The Agency believes this cost is sufficiently low that the candidate technology is cost-reasonable, and the BCT effluent limitations were proposed accordingly. The Agency will review all public comments and address the application of the BCT methodology to this subcategory when we promulgate the Gold Placer Mining regulations.

V. BCT Effluent Limitations Guidelines for Secondary Industries

A. Introduction

One major purpose of this rulemaking is to establish BCT effluent limitations for many of the secondary industries. EPA reviewed the status of BCT effluent limitations in each subcategory in the following industries: Dairy Products, Grain Mills, Canned and Preserved Fruits and Vegetables, Canned and Preserved Seafoods, Sugar Processing,

Cement Manufacturing, Feedlots, Fertilizer Manufacturing, Phosphate Manufacturing, Ferroalloy Manufacturing, Glass Manufacturing, Asbestos Manufacturing, Meat Products, and Mineral Mining and Processing. A summary of the results is shown in Table 1. The background data and calculations are reported in the record for this rulemaking.

The BCT cost test calculations for these industries were frequently based on cost and effluent data collected at the time of the original proposal and promulgation of BAT effluent limitations for each industry. If more current information regarding technology options and their economic achievability became available after promulgation of a final rule, EPA used that information to determine whether the technology satisfied all of the statutory requirements. Thus, the Agency is generally adopting previous findings concerning availability and effectiveness of treatment technologies.

In addition to the BCT cost test, section 304(b)(4)(B) of the Clean Water Act requires EPA to consider other factors such as the age of equipment, production process, and energy requirements when establishing BCT effluent limitations. Based on the rulemaking record for these industries and on this proceeding, EPA has determined that the final BCT effluent limitations following this preamble are technically feasible and otherwise satisfy section 304(b)(4)(B).

Today's regulation covers 135 subcategories (including subdivisions of subcategories); seven pass the BCT cost test and EPA is promulgating BCT limitations more stringent than BPT in these cases. For 88 of the remaining subcategories, BCT limitations are established equal to BPT limitations either because the candidate BCT technology fails the BCT cost test (48 subcategories) or because the Agency has not identified a technology that will achieve greater removals of conventional pollutants than achieved by BPT and also satisfy the requirements with respect to technical and economic feasibility (40 subcategories). For the remaining 40 subcategories, no action is taken with respect to BCT effluent limitations for one of two reasons. First, after reviewing existing limitations under the final BCT methodology, the Agency found that the existing limitations required no change, or second, the Agency has not completed a review of the candidate BCT technologies. A discussion of BCT regulations for each secondary industry follows.

B. Rationale for Establishing BCT Effluent Limitations and Changes Since Proposal

1. Dairy Products Processing (40 CFR Part 405)

The technology basis for the former BAT limitations was tertiary treatment by multimedia filtration. These BAT limitations addressed conventional pollutants only, and in 1979, were replaced by BCT limitations. Prior to the reproposal of BCT limitations in 1982, the Agency reviewed additional information regarding the filtration technology and determined that to ensure effective, year-round performance, it may be necessary to employ coagulation-sedimentation prior to filtration. This may be required because the suspended solids in biologically-treated dairy products processing wastewaters are difficult to treat, in that the excess solids can cause filter blinding and substantial operational difficulty. When the costs of coagulation-sedimentation are taken into account, none of the subcategories pass the BCT cost test. Additionally, EPA has not identified any other technology that results in further reduction of conventional pollutant discharges. Therefore, EPA is establishing BCT limitations equal to BPT limitations for all 12 subcategories in this industry. The final action for these subcategories is the same as the action proposed in 1982.

2. Grain Mills (40 CFR Part 406)

There are ten subcategories in this industry. For four subcategories (Normal Wheat Flour Milling, Normal Rice Milling, Animal Feed, and Hot Cereal), the BPT regulation requires zero discharge of process wastewater. BCT limitations for these four subcategories, established in 1979, already require zero discharge and remain substantively unchanged by this rulemaking because BCT limitations cannot be less stringent than BPT, and further levels of control do not exist beyond zero discharge. An editorial revision is made for these subcategories by incorporating the BPT requirement into BCT limitations by reference.

For the Corn Wet Milling Subcategory, BCT limitations were suspended in July 1980 (45 FR 45582) pending an evaluation of BPT costs. The Agency has not completed this evaluation, and the BCT limitations for this subcategory remain suspended.

The candidate BCT technology for the remaining five subcategories (Corn Dry Milling, Bulgur Wheat Flour Milling, Parboiled Rice Processing, Ready-to-Eat Cereal, and Wheat Starch and Gluten)

was filtration, which was the basis for the original BAT limitations. The Agency applied the BCT cost test to this technology for these five subcategories, and it failed, indicating that filtration is not cost-reasonable in these cases. No other candidate technology has been identified and, therefore, BCT limitations are promulgated equal to BPT. The final action for these five subcategories is the same as was proposed in 1982.

3. Canned and Preserved Fruits and Vegetables Processing (40 CFR Part 407)

The candidate BCT technology for the eight subcategories in this industry was filtration. This technology fails the BCT cost test, and no other suitable technology for the removal of conventional pollutants has been identified. Therefore, BCT limitations are established equal to BPT. The final action for this industry is the same as was proposed in 1982.

4. Canned and Preserved Seafood Processing (40 CFR Part 408)

There are 33 subcategories in this industry, and five are further subdivided by geographic location for purposes of this review. The candidate BCT technology for 12 subcategories and sections of two additional subcategories was dissolved air flotation, which was the technology basis for the former BAT limitations. This technology has not been widely applied at full scale, except for the Tuna Subcategory. Space requirements for installation of this technology present problems for many of the plants. EPA has determined, therefore, that dissolved air flotation is not feasible for the following subcategories: Non-Remote Alaskan Crab Meat Processing, Non-Remote Alaskan Whole Crab and Crab Section Processing, Dungeness and Tanner Crab Processing in the Contiguous States, Non-Remote Alaskan Shrimp Processing, Northern Shrimp Processing in the Contiguous States, Southern Non-Breaded Shrimp Processing in the Contiguous States, Breaded Shrimp Processing in the Contiguous States, Alaskan Mechanized Salmon Processing (Non-Remote), West Coast Hand-Butchered Salmon Processing, West Coast Mechanized Salmon Processing, Non-Alaskan Mechanized Bottom Fish Processing, Sardine Processing, Alaskan Herring Fillet Processing (Non-Remote), and Non-Alaskan Herring Fillet Processing. The Agency has not identified any other BCT candidate technology and is therefore establishing BCT effluent limitations equal to BPT effluent limitations for these subcategories.

The basis of BAT limitations in the Tuna Subcategory was optimized dissolved air flotation with chemically-assisted coagulation. The optimized operation adds operational complexity, maintenance requirements, and disposal costs for additional sludge volume. The Agency concludes that these operational difficulties are such that optimized dissolved air flotation is not technically feasible for the Tuna Subcategory. This technology was the only BCT candidate technology identified for the Tuna Subcategory. For these reasons, BCT effluent limitations are established equal to BPT effluent limitations.

In five other subcategories, the candidate BCT technology was aerated lagoons, which was the technology basis for the former BAT limitations. Based on information evaluated after BAT limitations had been issued, EPA determined that the technology is not feasible for Conventional Blue Crab Processing, Mechanized Blue Crab Processing, Non-Alaskan Conventional Bottom Fish Processing, Mechanized Clam Processing, and Steamed and Canned Oyster Processing. EPA determined that aerated lagoons are not a feasible technology for these subcategories because lagoons require a substantial amount of land, which is not uniformly available. Further, the seasonal and often sporadic processing operations of these plants do not provide the consistent source of wastewater needed for proper functioning of biological treatment systems such as aerated lagoons. EPA has not identified any other feasible technology providing further control of conventional pollutants than BPT. Therefore, EPA is establishing BCT limitations equal to BPT for these five subcategories.

The candidate technology for BCT for three other subcategories (characterized as remote Alaskan subcategories) and for the remote section of five additional subcategories was screening of the wastes and subsequent disposal of these wastes. EPA discovered technical problems with this technology, making it unsuitable as the basis for BCT limitations. The technology relies on solid waste disposal, which can be accomplished in non-remote areas by use of reduction facilities, but in remote areas, these facilities are not economically viable. Land disposal or barging are the most viable solid waste disposal techniques available to remote seafood processors, but these techniques are often not feasible or work only during a portion of the year because of weather. Therefore, EPA is establishing BCT limitations equal to

BPT for the following remote seafood subcategories and sections of subcategories: Remote Alaskan Crab Meat Processing, Remote Alaskan Whole Crab and Crab Section Processing, Remote Alaskan Shrimp Processing, and the remote section of Alaskan Hand-Butchered Salmon Processing, Alaskan Mechanized Salmon Processing, Alaskan Bottom Fish Processing, Alaskan Scallop Processing, and Alaskan Herring Fillet Processing.

The Agency is currently considering a petition from a portion of the Alaskan seafood industry requesting that EPA redesignate certain Alaskan cities from being considered "non-remote" and instead apply the effluent limitations guidelines and standards applicable to remote cities. If this petition were granted, the BPT effluent limitations guidelines for the affected locations would be based on grinding rather than screening technology. On May 18, 1980, EPA temporarily suspended the applicability of the BPT effluent limitations guidelines for non-remote facilities located in Anchorage, Cordova, Juneau, Ketchikan, and Petersburg pending review of the industry's petition (45 FR 32675). This notice explained that during the suspension period, facilities in these cities had agreed to comply with the regulations for the remote Alaskan processors. On January 9, 1981, EPA proposed its response to the petition and, at the same time, extended the suspension of the regulations for the affected cities until EPA makes a final decision on the petition (46 FR 2544). EPA has not yet taken final action on the petition; hence, BPT effluent limitations for the five cities listed above remain suspended.

In today's rulemaking, EPA is establishing some BCT limitations equal to BPT limitations for the cities in question. Therefore, this rulemaking imposes no additional burden on any facility. If, as a result of the pending petition, there is a change in the designation of a city from "non-remote" to "remote," that change will mean a change in the BPT and BCT effluent limitations that will apply. Since the BCT effluent limitations in this rulemaking establish limitations by cross referencing the BPT effluent limitations, where the BPT effluent limitations are suspended, the BCT effluent limitations will also be considered suspended until the BPT effluent limitations are promulgated. EPA is promulgating the BCT effluent limitations guidelines in their present form for the affected subcategories to

establish the framework to apply BCT effluent limitations in the future.

For the non-remote section of three Alaskan subcategories, EPA has not completed an economic impact analysis and is therefore reserving BCT effluent limitations for Alaskan Hand-Butchered Salmon Processing (non-remote), Alaskan Bottom Fish Processing (non-remote), and Alaskan Scallop Processing (non-remote).

After issuing the former BAT regulations for two other subcategories (Fish Meal and Hand-Shucked Clam Processing), EPA determined that the candidate technology, screening of wastes and process changes, would have resulted in substantial economic impact. For the Fish Meal Processing Subcategory, 12 of the 54 direct discharging plants would probably close as a result of the former BAT regulations. Most of these plants are small facilities. For the Hand-Shucked Clam Processing Subcategory, nine of the 15 direct dischargers would probably close rather than comply with the BCT regulations. These nine plants consist of all of the six small plants and all three of the canned clam plants in the subcategory. Based on these projected impacts, EPA concludes that the technology is not economically achievable. No other technology was identified as a candidate for BCT. For these reasons, EPA establishes BCT limitations equal to BPT in these subcategories.

The BCT cost test was applied to BCT candidate technologies for the remaining five subcategories. The candidate technology for Farm-Raised Catfish Processing includes screening, grease removal, and aerated lagoons. This technology fails the POTW test, and because no other candidate technology has been identified, BCT limitations are established equal to BPT.

The candidate technology for the remaining four subcategories relies on simple in-plant controls, which have only minimal costs and pass the POTW test. Since the incremental cost between BPT and BCT is considered to be zero, the second test ratio is also considered to be zero, and the technology passes the second test. Thus, EPA has determined that in-plant controls are technically feasible, economically achievable, and pass both parts of the BCT cost test for Pacific Coast Hand-Shucked Oyster Processing, Atlantic and Gulf Coast Hand-Shucked Oyster Processing, Non-Alaskan Scallop Processing, and Abalone Processing. The Agency proposed BCT limitations based on in-plant controls for these four subcategories and specifically requested

comments on the proposed decision. The Agency did not receive any adverse comments in response to that request, and no new information has been evaluated. Therefore, BCT limitations for these four subcategories are established based on in-plant controls. The final BCT limitations for this industry are the same as the BCT regulations that were proposed in 1982.

5. Sugar Processing (40 CFR Part 409)

There are eight subcategories in this industry. For two subcategories, BPT regulations require zero discharge of process wastewater. No technology more stringent than zero discharge exists and BCT cannot be established at a level less stringent than BPT. Therefore, EPA considers BCT requirements of zero discharge to be reasonable and is establishing BCT limitations equal to BPT for the Florida and Texas Raw Cane Sugar Processing Subcategory and the Hawaiian Raw Cane Sugar Processing Subcategory.

For the remaining six subcategories, EPA is also establishing BCT limitations equal to BPT because the candidate BCT technology fails the BCT cost test and no other candidate technology more stringent than BPT has been identified. These subcategories are Crystalline Cane Sugar Refining, Liquid Cane Sugar Refining, Louisiana Raw Cane Sugar Processing, Puerto Rican Raw Cane Sugar Processing, Hilo-Hamakua Coast of the Island of Hawaii Raw Cane Sugar Processing, and Beet Sugar Processing. For the first two of these six subcategories, the candidate technology is recirculation of barometric condenser cooling water and discharge of blowdown to an upgraded biological system. For the next two subcategories, the candidate technology is recycle of barometric condenser cooling water and cane wash water with the blowdown going to biological treatment. For the Hilo-Hamakua Coast subcategory, the candidate technology is recirculation of barometric condenser cooling water and biological treatment of both cane wash water and the blowdown from the recirculation system. For Beet Sugar Processing, the candidate technology is zero discharge of barometric condenser cooling water. Final BCT effluent limitations for all eight subcategories are the same as were proposed in 1982.

6. Cement Manufacturing (40 CFR Part 411)

Two of the three subcategories (Nonleaching and Materials Storage Piles Runoff) have BCT limitations equal to BPT. The Agency has not identified any other candidate technology that

provides additional control of conventional pollutants and, therefore, BCT effluent limitations in those two subcategories remain unchanged by this rulemaking. The BCT candidate technology for the remaining subcategory, Leaching, is treatment and reuse. This technology fails the BCT cost test, no other candidate technology has been identified, and BCT limitations are established equal to BPT. This action is the same as the 1982 proposed action for the Leaching Subcategory.

7. Feedlots (40 CFR Part 412)

The Feedlots category consists of two subcategories. For the first (All Subcategories Except Ducks), BCT limitations are primarily based on zero discharge of process wastewater pollutants. The 1982 proposed action for this subcategory would have removed the section for BCT effluent limitations because the existing BCT limitations are more stringent than BPT limitations due to the rainfall event specified for discharge of pollutants from the overflow. The Agency has not evaluated the cost of the more stringent overflow restriction according to the BCT methodology. Therefore, the existing section is removed and reserved. The existing BAT limitations, however, remain unchanged; they also require zero discharge of process waste pollutants with the more restrictive condition for discharge from overflow.

For the second subcategory (Ducks), conventional pollutant discharges from man-made or natural (e.g., marshes) swimwater areas are difficult to quantify. These discharges are also difficult to adapt to traditional end-of-pipe treatment technologies. The technology basis for BAT (and the candidate BCT technology) was dry lots, but the effluent reduction benefits between existing discharges and dry lots cannot readily be quantified. Therefore, the BCT cost test cannot be performed. EPA did not propose, and is not now establishing BCT effluent limitations guidelines for duck feedlots.

8. Fertilizer (40 CFR Part 418)

The Agency has not established effluent limitations guidelines to control conventional pollutant discharges for three of the seven subcategories in this category: Urea, Ammonium Nitrate, and Nitric Acid. The existing BPT and BAT requirements for those subcategories do not address conventional pollutants. Therefore, no action is taken with respect to BCT for these three subcategories; there are no BCT effluent limitations guidelines. For two other subcategories (Ammonium Sulfate Production and Mixed and Blend

Fertilizer Production), BCT limitations based on zero discharge of process wastewater pollutants have already been promulgated. In both of these subcategories, the BPT regulations are also based on zero discharge and, therefore, no evaluation by the BCT cost test is necessary.

For the Phosphate Subcategory, BCT limitations based on zero discharge have already been promulgated but with discharge allowances for specified rainfall events. No more stringent candidate technology for control of conventional pollutants has been identified; the existing BCT limitations for the Phosphate Fertilizer Subcategory remain unchanged. On July 25, 1984, the Agency proposed to amend the applicability section for Phosphate Fertilizer to exclude four plants in Louisiana from BAT and BCT effluent limitations (49 FR 29977). Final action on this amendment is pending and is not affected by today's rulemaking.

For the Ammonia Subcategory, BCT limitations have already been promulgated equal to BPT. The Agency has not identified any other candidate technologies that would result in additional control of conventional pollutants. Therefore, no change is being made to the BCT effluent limitations for this subcategory. The BAT limitations for the Ammonia Subcategory are being revised to remove the limitation for pH, which is a conventional pollutant and cannot be included in the BAT limitations. Instead, it is included in the BCT limitations.

This rulemaking also includes minor editorial corrections for the Phosphate and Ammonia Subcategories to correct the titles in the table of contents.

9. Phosphate Manufacturing (40 CFR Part 422)

The Phosphate category covers six subcategories. Three subcategories (Phosphorus Production, Phosphorus Consuming, and Phosphate) do not have any regulations in effect; they consist of applicability sections only. EPA is not establishing BCT limitations for these subcategories at this time. Two other subcategories (Defluorinated Phosphate Rock and Defluorinated Phosphoric Acid) already have BCT limitations equal to BPT; no further analysis is required because both regulations are based on zero discharge with effluent limitations for specified rainfall events. The existing BCT requirements for these subcategories remain unchanged by this final action. For the remaining subcategory, Sodium Phosphates, the candidate technology is increased recirculation of process wastewater, which passes the BCT cost test. The

incremental costs are estimated to be minimal in that any costs attributed to reducing the flow to the treatment system are offset by the smaller amount of lime needed. Therefore, BCT limitations at the BAT level of control are reasonable and are so established. This level of control is the same as was proposed in 1982.

10. Ferroalloy Manufacturing (40 CFR Part 424)

One of the seven subcategories (Other Calcium Carbide Furnaces) has BCT limitations equal to BPT already in effect; both BCT and BPT require zero discharge of process wastewater pollutants. No other technology provides additional control and therefore, the existing BCT limitations remain unchanged. Candidate technologies for the remaining six subcategories rely on partial recycle and physical-chemical treatment of blowdown (plus filtration for the Calcium Carbide Furnace Subcategory), which fails the cost test. No other candidate technologies have been identified and, therefore, BCT limitations are established equal to BPT for these subcategories.

This final action encompasses one change from the BCT limitations proposed in 1982. When the candidate technology for the Slag Processing Subcategory was evaluated with the 1982 proposed benchmarks, it passed the cost test, and BCT limitations were proposed at a level more stringent than BPT limitations. The benchmarks in this final action are lower than the benchmarks proposed in 1982, and while the candidate technology for the Slag Processing Subcategory still passes the POTW test, it fails the industry cost test. Therefore, BCT limitations are established at a less stringent level of control than was proposed (i.e., equal to BPT instead of equal to BAT).

11. Glass Manufacturing (40 CFR Part 426)

Two of the 13 subcategories (Sheet Glass and Rolled Glass) have BCT and BPT requirements based on zero discharge already in effect; those subcategories remain unchanged by this final action. Candidate technologies for eight other subcategories are as follows. For the Plate Glass Subcategory, the candidate technology is effluent recycle and sand filtration. For Float Glass, Automotive Glass Tempering, and Automotive Glass Laminating, the candidate technology is diatomaceous earth filtration. For the Glass Container Subcategory, the technology is recirculation of cullet quench water, dissolved air flotation, and

diatomaceous earth filtration of the blowdown. The candidate technology for Glass Tubing is the same as for Glass Container without dissolved air flotation. For the Television Picture Tube Envelope Subcategory, the candidate technology is sand filtration. For the Incandescent Lamp Envelope Subcategory, the technology is sand filtration for frosting wastewaters and diatomaceous earth filtration of the cullet quench water. These technologies fail the BCT cost test, and no other candidate technology has been identified. For these reasons, BCT limitations were proposed and are now established equal to BPT for those eight subcategories.

For the Insulation Fiberglass Subcategory, BPT requirements are based on zero discharge with specific limitations on the discharge of conventional pollutants from wet air pollution control devices. The candidate BCT technology is zero discharge from all sources, including air pollution control devices. The Agency lacks sufficient data to quantitatively evaluate the candidate BCT technology with the BCT cost test. However, based on estimates of the incremental cost of additional flow restrictions (which are crucial to the candidate technology), the Agency believes the candidate technology is not cost reasonable and is establishing BCT limitations equal to BPT.

In the Hand Pressed and Blown Glass Subcategory, there are no BPT effluent limitations for any pollutants. The Agency is considering proposing BPT regulations that would result in a nationally applicable base level of treatment being required for this subcategory. Effluent limitations based on BCT will be evaluated at the same time. Therefore, BCT limitations for the Hand Pressed and Blown Glass Subcategory are being removed and reserved. This rulemaking also includes revisions to the BAT limitations for the Hand Pressed and Blown Glass Subcategory and the Incandescent Lamp Envelope Subcategory. The corrections remove conventional pollutant limitations from the BAT sections in those subcategories.

The remaining subcategory, Machine Pressed and Blown Glass Manufacturing, has been reserved. No regulations are currently in effect, and no action is taken with regard to BCT limitations.

12. Asbestos Manufacturing (40 CFR Part 427)

One of the 11 subcategories, Solvent Recovery, has BCT limitations equal to BPT already in effect. No other

technology for removing conventional pollutants has been identified, and the existing BCT limitations for this subcategory are not affected by this rulemaking. For the remaining ten subcategories, no action is being taken with respect to BCT limitations. BCT limitations have not been proposed for any of these ten subcategories, and therefore, none are established at this time.

13. Meat Products (40 CFR Part 432)

The original BAT limitations for eight of the ten subcategories in this category were based on nitrification. Those BAT limitations were subsequently withdrawn, pending a review of the feasibility of that technology. The Agency concluded that biological nitrification was not a suitable technology basis for BCT. One significant factor is that nitrification effects removal of ammonia nitrogen from these wastewaters, but affords only small removals of conventional pollutants beyond BPT levels. Further, a key part of the former BAT limitations was reduction in water use in meat processing operations, which may not be achievable in many plants. Finally, preliminary results of the technology review indicated that consistent, year-round removal of conventional pollutants beyond BPT is technically achievable only with extraordinary operational care. For these reasons, EPA has rejected nitrification as the basis for BCT. No other technologies have been identified, and BCT limitations are therefore established equal to BPT for the eight subcategories.

For the remaining two subcategories, Small Processors and Renderers, the candidate technology is in-plant controls (the former BAT). This technology passes the BCT cost test, and BCT limitations are established at the BAT level of control. For both subcategories, the incremental costs associated with the former BAT limitations are minimal. The Agency concluded that these costs were reasonable and proposed, and now promulgates, BCT limitations accordingly. The Agency did not receive any comments objecting to the proposed level of control.

14. Mineral Mining and Processing (40 CFR Part 436)

This category contains 38 subcategories; 17 have no regulations in effect; the remainder have BPT regulations only. While some of the BPT regulations are based on zero discharge of process wastewater pollutants, the Agency has not yet proposed any BCT limitations for this category. This final

rulemaking does not contain regulations for any of the subparts of this category.

VI. Anti-Backsliding

In order to implement the Clean Water Act goal of continued further progress toward eliminating pollutant discharges, EPA established an "anti-backsliding" policy reflected in the NPDES regulations at 40 CFR 122.44(1). See *U.S. Steel v. Train* 556 F.2d 822, 842 (7th Cir., 1977). Generally, this provision prohibited the reissuance of an NPDES permit with limitations, standards, and conditions less stringent than those in the previous permit. However, the NPDES regulations contained an exception to this anti-backsliding policy at 40 CFR 122.44(1)(2)(iii) for subsequently promulgated effluent limitations guidelines based on BCT. In September 1984, the Agency revised several other parts of the NPDES rules. In that revision, EPA recognized that the BCT exception is inconsistent with the general intent of the anti-backsliding policy (49 FR 37998 and 38021, September 26, 1984). The Agency agreed with a commenter's statement that BCT effluent limitations must in all cases be at least as stringent as BPT effluent limitations, whether those BPT limitations are included in a guideline or are in a permit based on best professional judgment (BPJ). Therefore, the preamble to the 1984 NPDES rule noted that EPA would assess the need to correct the anti-backsliding policy in conjunction with issuance of a final BCT methodology.

There may be cases where BPJ permits are more stringent than BCT effluent limitations. Thus, EPA intends to propose amendments to 40 CFR 122.44(1) to correct the anti-backsliding regulations and remove the exception concerning BCT effluent limitations.

VII. Availability of Fundamentally Different Factors Variances

Upon promulgation of this regulation, the appropriate effluent limitations must be applied in all Federal and State NPDES permits thereafter issued to direct dischargers. For BCT limitations, the only exception to the binding limitation is EPA's "fundamentally different factors" (FDF) variance. The FDF variance recognizes factors concerning a particular discharger that are fundamentally different from the factors considered in this rulemaking. However, the economic ability of the individual operator to meet the compliance cost for BCT is not a consideration for granting a variance. See *National Crushed Stone Association v. EPA* 449 U.S. 64 (1980) (Evaluating

FDF variances from BPT). See also the NPDES regulations at 40 CFR Part 125, Subparts A and D (45 FR 14166 et seq., April 1, 1983) for the text and explanation of the FDF variance.

This rulemaking references the availability of the FDF variance in each section where the Agency is establishing BCT effluent limitations guidelines. Some prior BCT regulations that are not changed by today's rulemaking did not specifically cross reference the FDF variance provision. Under the terms of the FDF regulations, the FDF variance is available for all BCT effluent limitations regardless of whether or not the text of a BCT regulation specifically indicates the availability of FDF variances.

VIII. Regulatory Analysis Requirements

A. Regulatory Flexibility Analysis

Pub. L. 96-354 requires EPA to prepare a Regulatory Flexibility Analysis for regulations that have a significant impact on a substantial number of small entities. This analysis may be prepared in conjunction with or as part of other Agency analysis. In support of previous rulemakings for the industries covered by today's regulation, EPA conducted analyses to evaluate the impacts on small entities. No potential for significant impact was projected. An exception to this conclusion is for the seafoods industry, where an economic analysis projected significant economic impact for certain small plants (See Section IV). EPA is setting BCT effluent limitations equal to BPT effluent limitations for these plants; therefore, there is no incremental effect associated with this regulation for these small plants.

No new significant impacts on small businesses are expected as a result of today's final regulation. Therefore, a formal Regulatory Flexibility Analysis is not required. The previous analyses and small business definitions are included in the record.

B. Regulatory Impact Analysis

Executive Order 12291 requires EPA and other agencies to perform regulatory impact analyses of major regulations. Major rules impose an annual cost to the economy of \$100 million or more or meet certain other economic impact criteria specified in the Order. The expected cost of today's regulation on industry is significantly less than \$100 million per year, and none of the other criteria are met. This action, therefore, is not a major regulation as defined by E.O. 12291 and no Regulatory Impact Analysis is required. For future BCT rulemakings, the Agency will again consider whether the final BCT effluent

limitations represent a major regulation in light of the cost and impact to the specific industry.

IX. Response to Major Comments

EPA received public comments on the October 1982 proposal from 44 industrial concerns (firms and trade associations) and one state environmental protection agency. All comments were carefully considered and appropriate changes adopted whenever data and information supported those changes. Five methodological changes to the proposal were highlighted in the 1984 notice of data availability. The Agency received comments from 17 parties concerning the BCT methodology in response to the September 1984 notice. Five issues from those comments are addressed below. All of the comments on the 1982 proposal and the 1984 notice and our detailed responses are included in two documents: "BCT Comments and Responses—Proposed Methodology and Limitations" and "Response to Comments, BCT Notice of Data Availability." Both documents are included in the record for this rulemaking. The remainder of this section presents the most significant comments received on the 1982 proposal and 1984 notice and our responses.

A. Major Comments from the 1982 Proposed Rule

1. Use of Advanced Secondary Treatment

Comment: Commenters questioned the use of the incremental costs of secondary to advanced secondary treatment as the basis for developing the POTW benchmark. Specific comments regarding the use of advanced secondary treatment focused on statutory authority and Congress' intentions with respect to the methodology.

Response: The criticisms of using advanced secondary treatment were initially raised prior to the 1982 proposal. In fact, many of these criticisms were raised when EPA published the 1979 BCT methodology and were specifically rejected by the U.S. Court of Appeals for the Fourth Circuit in *American Paper Institute v. EPA* 60 F.2d 954 (4th Cir. 1981). While the Clean Water Act does not mention advanced secondary treatment in reference to BCT, the Court of Appeals accepted its use in this context.

The final BCT methodology continues to rely on the same comparison as was proposed; that is, an industry's cost to control conventional pollutants beyond BPT is compared to a POTW cost for control beyond secondary treatment.

The cost basis for industry is the increment between BPT and BCT; the cost basis for POTWs is the increment between secondary treatment and advanced secondary treatment. While the 1981 court decision affirmed EPA's choice of analyzing costs beyond the secondary treatment level, some commenters observed that the repeal of section 301(b)(2)(B) of the Clean Water Act affected EPA's statutory authority for relying on the cost of advanced secondary treatment in the BCT methodology since it was section 301(b)(2)(B) that had required POTWs to achieve treatment beyond secondary. The Agency believes, however, that the increment of secondary treatment to advanced secondary treatment is both correct and consistent with the statute. As stated in the August 29, 1979 final regulation (44 FR 50735) and in Section III.A above, there remain three reasons for EPA's choice of the secondary to advanced secondary increment. First, this increment yields an approximation of marginal costs at secondary treatment. Second, advanced secondary treatment is the "knee-of-the-curve" with respect to POTW costs. Finally, the level of treatment for a POTW to upgrade from secondary to advanced secondary treatment roughly parallels the industrial increment under consideration.

In order to compare the benchmark to an industry's cost of removing additional pounds of conventional pollutants, the benchmark and industry cost must be evaluated consistently. The final BCT methodology achieves this analytical consistency with the parallel between secondary treatment for POTWs and the BPT level of control for industrial dischargers. The treatment technology is often similar, the level of pollutant reduction is often similar, and the level of regulatory control is similar in that both secondary treatment and BPT represent a minimum level of control. The BCT methodology then poses a question of whether to control conventional pollutants beyond this minimum level; i.e., "beyond BPT." Therefore, the comparison to the POTW cost should also reflect control beyond the minimum level; i.e., "beyond secondary."

2. Weighting of POTW Flows

Comment: Some commenters criticized the flow-weighting scheme used in the proposal and suggested alternative approaches. Other commenters stated that those criticisms were unfounded and supported the Agency's use of a flow-weighted average cost per pound and also

supported the Agency's proposed weighting scheme.

Response: The Agency evaluated alternative approaches to a weighting scheme and concluded that none were appropriate. For example, weighting by total incremental costs for each scale of POTWs would weight the high cost plants more heavily simply because they have high costs, rather than because they remove large amounts of pollutants. Another alternative, weighting by total incremental pounds, produced similar results to the approach the Agency proposed. A third suggestion, weighting both flow and the number of POTW, heavily weights the smaller POTWs and biases the incremental costs upwards. This result is also not representative of the expenditures made on POTWs.

The Agency's overall response is that the proposed flow-weighting scheme is appropriate in terms of representing various sizes of POTWs, is more reliable than using cost data for a single point, and correctly corresponds to the approach used to estimate industry costs. Therefore, use of the proposed flow-weighting scheme is maintained in the final methodology.

3. Establishing a Benchmark for the Second Test

Comment: Several commenters responded to the Agency's solicitation regarding an appropriate measure for the industry cost test benchmark. Some of these comments supported the concept of elasticity of unity (using a benchmark of 1.0) as a more appropriate measure than the increasing cost ratio.

Response: The Agency disagrees with comments that the elasticity of unity should be applied because it has no significant bearing on determining cost-effectiveness, which is the objective of the second test. Further, from a practical point of view, as mentioned in the comments, EPA does not have enough data to use the elasticity of unity approach. For almost all of the secondary industries, the Agency has cost and pollutant removal data for only one BCT candidate technology (generally the original BAT technology). As a consequence, it is not possible to identify the point where elasticity is one. The basis for the second test benchmark in the final methodology remains the increasing cost ratio. Most of the comments received on this issue were not opposed to the Agency's approach.

4. POTW Cost Data

Comment: Some comments received in response to the 1982 proposal plus comments received in response to a subsequent notice concerning POTW cost data (48 FR 24742, June 2, 1983)

criticized EPA's use of actual POTW costs in deriving POTW cost curves. Commenters believed that site-specific factors dwarfed the cost differentials associated with improving POTW effluent performance from secondary to advanced secondary treatment. Substantial concerns were expressed with regard to the validity of the POTW cost data.

Response: For the 1982 proposal, the Agency based its estimates of POTW costs on actual plants' experiences regarding the costs of constructing and operating POTWs. In 1983, more up-to-date information of a similar nature was available, and the Agency issued a notice indicating its intentions to use the new data as the basis for calculating the benchmarks.

Following that notice, the Agency became aware that the new data might not be appropriate for use in the BCT methodology. The Agency's analysis of the new data was prompted, in part, by comments from the industry. The costs of secondary and advanced secondary treatment, as derived from the new data, varied substantially due to site-specific factors. The resulting incremental costs were determined to be unsuitable for use in the BCT methodology. The Agency also realized that the data used in the 1982 proposal might be subject to similar problems. Consequently, the new data were withdrawn, and after further evaluation, the Agency concluded it was necessary to use a different data source for POTW costs. The selected approach was to develop model POTW costs. The Agency presented the model POTW costs in detail in the September 1984 notice. Comments concerning that notice are presented below (under Heading B.)

5. Choice of Effluent Level to Define Advanced Secondary Treatment

Comment: One commenter stated that the selection of 10 mg/l as the achievable concentration for both BOD and TSS (the level proposed in 1982) was not representative of POTW performance at advanced secondary treatment. The same commenter also noted that the operational definition of advanced secondary treatment has been described in EPA documents as ranging from 10 mg/l to 25 mg/l for both BOD and TSS, rather than as a single, legally defined value, such as 30 mg/l is for secondary treatment. An industry organization submitted a rebuttal comment, asserting that there was no need for EPA to change the definition of advanced secondary treatment.

Response: EPA re-examined the data and is now defining advanced secondary treatment as a maximum 30-day average concentration of 20 mg/l BOD and 20 mg/l TSS. EPA indicated its

intent to use this definition in the 1984 notice and received supportive comments. EPA believes this level represents typical permit limitations for advanced secondary facilities and has applied this definition to several aspects of the methodology. First, EPA applied this definition to the design specifications for estimating POTW costs. Second, when estimating the long-term performance for advanced secondary POTWs, EPA included a permit limitation of 20 mg/l BOD in the editing criteria.

The Agency recognizes there is no single, generally-accepted definition for advanced secondary treatment as there is for secondary treatment. EPA's analysis of actual permit data showed that 20 mg/l BOD is the most common permit requirement for POTWs beyond secondary treatment. The Agency believes that concentrations of 20 mg/l BOD and TSS represent the best definition of advanced secondary treatment for purposes of the BCT methodology.

When the Agency changed its approach for estimating POTW costs, these comments concerning the definition of advanced secondary treatment became less relevant. For the proposal in 1982, a change in definition alone would affect the calculation of incremental pollutant removals and the resulting benchmarks. For the final methodology, where the model POTWs reflect specific treatment systems for specific performance levels, the calculation of pollutant removals is affected by both definition and cost. Therefore, the computational "side-effects" of changing the definition are very different than would have been true when this comment was originally made.

6. Use of Pre-BPT and Pre-Secondary Treatment Levels

Comment: Various industry commenters complained that EPA's inconsistent definition of pre-BPT treatment levels would result in inconsistent BCT calculations. They noted that these inconsistencies would lead to misleading conclusions regarding the cost per pound of pollutant removed for BPT and would bias the industry cost test against certain industries.

In selecting the previous pre-BPT levels for industrial categories and subcategories, EPA attempted to choose treatment levels existing at the time BPT effluent limitations guidelines were developed. Commenters criticized the subjectivity involved in selecting this treatment level. They also pointed out that this "treatment-in-place" level

could not be developed for all industry categories, forcing EPA to assume no treatment for some industries. By using both "treatment-in-place" and "no treatment," EPA introduced inconsistencies and biases that were based either on whether an industry had substantially complied with BPT effluent limitations guidelines before their promulgation or on the availability of data to conduct the calculations. Commenters asserted that these factors should not be a consideration in determining the stringency of BCT effluent limitations guidelines. Commenters suggested two ways to improve the computation. First, some commenters suggested that EPA collect new data to employ the "treatment-in-place" method for all industry categories. Second, other commenters suggested that EPA base all pre-BPT calculations on raw waste (i.e., no treatment).

Response: EPA agrees with the criticisms and is therefore establishing the pre-BPT treatment level for all industry categories as raw waste. EPA also recognizes that the primary treatment level for POTWs that was used in the proposal cannot be considered equivalent to raw waste for industry. Therefore, EPA is using raw waste as the pre-secondary treatment level for POTW cost and pollutant reduction calculations. These changes were presented in the 1984 notice and are maintained in the final BCT methodology. EPA concludes that a consistent application of raw waste as the "starting point" for both industry and POTW calculations addresses the commenters' concerns.

7. Use of Long-Term Average Effluent Concentrations

Comment: The Agency received several comments opposing the use of 30-day maximum effluent limitations in pollutant removal calculations. Commenters claimed that the use of 30-day limitations biases the test against industries whose "variability factors" are larger than those for POTWs. A "variability factor" is the ratio of the 30-day maximum effluent limitation to a long-term effluent concentration. The use of 30-day maximum limitations was said to bias the test against the industry by overstating the number of incremental pounds of pollutants removed by BCT.

For industry calculations, the commenters also noted that EPA based removals on 30-day limitations for the BPT and BCT levels, while using long-term averages for pre-BPT levels (both treatment-in-place and raw wasteload).

Commenters asserted that this biased the dollar per pound calculations for both the BPT and BCT incremental treatment levels. The calculation overstates the actual pounds removed in going from BPT to BCT, and understates the actual pounds removed in going from pre-BPT to BPT.

Commenters suggested several ways to correct these biases. The suggestions focused on the long-term data.

Response: EPA recognizes the merits of these comments and has changed the industry and benchmark calculations as follows. For industry calculations, EPA is using annual average effluent levels (which are considered long-term) for raw waste, BPT, and BCT. For POTW calculations, EPA uses annual average effluent levels for raw waste, secondary treatment, and advanced secondary treatment. In summary, the long-term average effluent concentrations are applied at all treatment levels for both industry and POTW calculations. This approach was presented in the 1984 notice, was supported by commenters (see Comment No. 11, below), and is maintained in the final BCT methodology.

An exception to using long-term average concentrations occurs for many of the secondary industries, where, due to data constraints, EPA can only conduct the industry calculations at BPT and BCT levels using the 30-day maximum limitations. To reduce the possible bias that would exist if these secondary industry calculations were compared to BCT benchmarks based on long-term averages, EPA established a second tier of benchmarks that correspond to the industry calculations. These second tier benchmarks are based on 30-day limitations for secondary and advanced secondary treatment. This solution was presented in the 1984 notice and did not receive opposition. The two-tier approach is maintained in the final methodology.

To summarize, using long-term average concentrations is the preferred approach. The benchmarks in this final rulemaking are derived from long-term effluent data. Industry calculations will also be based on long-term effluent data. When the preferred approach is not feasible due to limitations on long-term data (as is true for many of the secondary industries), a second tier of benchmarks will be applied so that the BCT cost test is conducted on a consistent basis.

B. Major Comments From the 1984 Notice of Data Availability

8. Variation Among the Model Plant Cost Estimates

Comment: Commenters questioned the reliability and accuracy of the POTW cost estimates due to the variation in results. Costs from the three engineering firms were to be based on the same basic design criteria, but the commenters found the variation in results to be inexplicable. The comments also argued that the Agency's estimates of the incremental cost to reach advanced secondary treatment were much too high.

Response: The Agency provided limited design specifications on size, general operating conditions, required effluent levels, and basic treatment processes to three engineering design firms with experience in POTW development. Specific design criteria were determined by each firm to take maximum advantage of their experience and expertise. EPA did not want to prejudice the end result by providing overly detailed directions to the design firms.

One reason for the large variation among the incremental total annual costs was one firm's design assumption regarding the use of alum in the chemical addition step for advanced secondary treatment. While the addition of alum does reduce the level of solids in the final effluent, alum addition greatly increases the sludge handling requirements with a corresponding increase in cost. Alum is generally used to remove phosphorus. The Agency concluded that addition of alum is not the most appropriate choice for the model POTWs to be used in the BCT methodology. The more common chemical additive is polymer, which was chosen by the two other design firms. The general design criteria were adjusted by specifying that chemical addition be the addition of a polymer.

Other corrections and minor revisions were also made as a result of comments on specific engineering assumptions. The variation among incremental total annual costs in the current estimates is much smaller than the variation in costs in the September 1984 notice. For example, in the 1984 notice, the incremental total annual costs for the 25 mgd model POTW ranged from \$0.40 million to \$1.53 million. The current estimates used in today's regulation range from \$0.34 million to \$0.48 million. In addition, the average incremental costs (which are the values used in the benchmark calculations) are

significantly lower than the average incremental costs in the 1984 notice.

9. Use of Planning Level Estimates in Benchmark Calculations

Comment: Some commenters encouraged inclusion of "planning level" estimates for the large model POTWs. Their arguments claimed the planning level estimates are no less accurate than the design estimates.

Response: In addition to the design estimates provided by three firms, EPA directed a fourth engineering firm to develop planning level estimates. Two sources of information were used for the planning level estimates: available planning level cost curves and the CAPDET cost estimating computer program.

Planning level estimates are typically used by engineers during preliminary analyses of a wide range of alternatives. Their greatest application is as a screening tool, whereby alternatives having obviously high costs are eliminated from further analysis. The accuracy of planning level estimates is typically within 30 percent of the final cost of a project, while for design estimates, accuracy is in the range of 10 to 15 percent. The Agency obtained detailed design cost estimates for the large POTW sizes because the incremental cost implication for upgrading large facilities is of much greater significance than for upgrading small facilities due to the flow-weighting factors assigned in the benchmark calculations. The planning level estimates were prepared for all five sizes of model POTWs, but they were used only for the two smallest sizes. The calculations for the three larger sizes continue to be based solely on the design estimates.

10. Presentation of Data in Engineering Reports

Comment: Some commenters claimed that the level of detail provided in the engineering reports was inadequate. The reports were further criticized for their lack of design drawings. The commenters claimed the presentation of data precluded adequate review by the public, and they urged further disclosure of background information and a reopening of the comment period.

Response: The reports from the design firms all followed a similar format for presentation of information. Treatment systems and costs were described for each POTW; the amount of detail provided was substantial for structures and equipment. Similarly, the assumptions and costs for operating and maintenance were presented in detail. In response to the lack of drawings, the

Agency notes that it is standard engineering practice to develop detailed design drawings to fit particular sites. The hypothetical nature of the model POTWs makes preparation of drawings (other than general sketches of equipment arrangement or to prepare construction quantity estimates) inappropriate.

EPA firmly believes that the information needed to analyze the contractors' work was available. We do not believe that additional information was necessary to review or evaluate the cost estimates; reopening the 105-day comment period was not necessary.

11. Appropriateness of Long-Term Average Concentrations

Comment: Commenters believe the Agency incorrectly calculated long-term average effluent concentrations for POTW treatment levels. Specifically, their criticism focused on the choice of POTWs included in the performance analysis. Commenters asserted that problems with the editing criteria resulted in an incorrect assessment of incremental pollutant removals.

Response: It is important to note that commenters generally supported the use of long-term averages instead of maximum 30-day limitations, which had previously been used in the methodology. Also, they generally supported the Agency's use of the POTW performance data base. Their objections focused on the specific values that were identified as the long-term average concentrations. EPA recognized that some of the commenters' concerns warranted additional analyses, which have since been conducted and are discussed in Section III.D.

The editing criteria specify a permit limitation and the conditions for complying with the limitation. The Agency revised the editing rule on violations to allow both pollutants to exceed the permit requirement if that situation occurs in the same month; this revision accounts for the relationship between the pollutants. Editing criteria were also added to better define the treatment systems for secondary and advanced secondary treatment POTWs. Further, the criteria now exclude POTWs that were performing at levels much better than would be characteristic of secondary and advanced secondary treatment. The revised editing criteria, which respond to the commenters' concerns, were used to calculate the long-term averages for the final benchmarks.

12. Reproposing BCT Methodology and Effluent Limitations Guidelines

Comment: Several commenters submitted procedural objections to the notice of data availability. They claimed that the changes in the September 1984 notice were significant enough departures from the October 1982 proposal to warrant reproposal of the methodology and effluent limitations guidelines.

Response: The changes presented in the September 1984 notice were all in response to, and were logical outgrowths of, comments submitted on the October 1982 proposal. As an example, one commenter had strongly criticized the empirical cost data that were being considered; this comment influenced the Agency's decision to develop model POTW costs.

The comments concerning reproposal emphasized the need for meaningful comment. EPA believes this need has adequately been met. When the September 1984 notice was published, the Agency notified all parties who submitted comment on the earlier proposal, making a special effort to give them opportunity to comment on the new information. This opportunity was further facilitated by a 45-day extension to the comment period. Also, the major commenters from October 1982 all submitted further comments in September 1984. Therefore, EPA believes that all interested parties had ample opportunity to submit meaningful comments and that reproposal is not necessary.

X. Availability of Technical Information

The costs and pollutant removal data that were used to support the industry calculations for the secondary industries were taken from the development documents and economic analyses that were published in the development of BAT effluent limitations guidelines. These documents are available for review as part of the record for this rulemaking (in EPA's library) and at all EPA regional libraries.

POTW cost data used to calculate the final benchmarks are documented in reports from each of the engineering firms that provided model POTW cost estimates. Those costs, the benchmark calculations, and results are presented in an additional report, "BCT Benchmarks: Methodology, Analysis and Results." All of these documents are available for review as part of the record in EPA's library.

XI. OMB Review

This regulation was submitted to the Office of Management and Budget for

review as required by Executive Order 12291. This rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Comments from OMB to EPA and EPA's responses are available for public inspection as part of the record for this rulemaking.

List of Subjects

40 CFR Part 405

Dairy products, Water pollution control, Waste treatment and disposal.

40 CFR Part 406

Grains, Water pollution control, Waste treatment and disposal.

40 CFR Part 407

Fruits, Vegetables, Water pollution control, Waste treatment and disposal.

40 CFR Part 408

Seafood, Water pollution control, Waste treatment and disposal.

40 CFR Part 409

Sugar, Water pollution control, Waste treatment and disposal.

40 CFR Part 411

Cement industry, Water pollution control, Waste treatment and disposal.

40 CFR Part 412

Feedlots, Livestock, Water pollution control, Waste treatment and disposal.

40 CFR Part 418

Fertilizers, Water pollution control, Waste treatment and disposal.

40 CFR Part 422

Phosphate, Water pollution control, Waste treatment and disposal.

40 CFR Part 424

Iron, Metals, Water pollution control, Waste treatment and disposal.

40 CFR Part 426

Glass and glass products, Water pollution control, Waste treatment and disposal.

40 CFR Part 432

Meat and meat products, Water pollution control, Waste treatment and disposal.

Dated: May 19, 1986.

Lee M. Thomas,
Administrator.

For the reasons set out in the preamble, 40 CFR Parts 405, 406, 407, 408, 409, 411, 412, 418, 422, 424, 426, and 432 are amended as follows:

1. The title of Part 405 is revised to read as follows:

PART 405—DAIRY PRODUCTS PROCESSING POINT SOURCE CATEGORY.

2. The authority citation for Part 405 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c) and 307(c) of the Federal Water Pollution Control Act, as amended (the Act); 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), and 1317(c); 86 Stat. 816, et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 405.17, 405.27, 405.37, 405.47, 405.57, 405.67, 405.77, 405.87, 405.97, 405.107, 405.127 [Added]

§ 405.117 [Revised]

3. Sections 405.17, 405.27, 405.37, 405.47, 405.57, 405.67, 405.77, 405.87, 405.97, 405.107, and 405.127 are added, and § 405.117 is revised. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 405. Column (b) indicates the section number to be added to the text of the section indicated in column (a).

Subpart	(a) Section number to be added to section heading	(b) Section number to be added to text of the section in (a)
Subpart A—Receiving stations subcategory.....	405.17	405.12
Subpart B—Fluid products subcategory.....	405.27	405.22
Subpart C—Cultured products subcategory.....	405.37	405.32
Subpart D—Butter subcategory.....	405.47	405.42
Subpart E—Cottage cheese and cultured cream cheese subcategory.....	405.57	405.52
Subpart F—Natural and processed cheese subcategory.....	405.67	405.62
Subpart G—Fluid mix for ice cream and other frozen desserts subcategory.....	405.77	405.72
Subpart H—Ice cream, frozen desserts, novelties and other dairy desserts subcategory.....	405.87	405.82
Subpart I—Condensed milk subcategory.....	405.97	405.92
Subpart J—Dry milk subcategory.....	405.107	405.102
Subpart K—Condensed whey subcategory.....	405.117	405.112
Subpart L—Dry whey subcategory.....	405.127	405.122

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the

following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § (b) of this subpart for the best practicable control technology currently available (BPT).

PART 406—GRAIN MILLS POINT SOURCE CATEGORY

1. The authority citation for Part 406 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 406.27, 406.67, 406.97, 406.107 [Added]

§§ 406.37, 406.47, 406.57, 406.77, 406.87 [Revised]

2. Sections 406.27, 406.67, 406.97, and 406.107 are added, and §§ 406.37, 406.47, 406.57, 406.77, and 406.87 are revised. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 406. Column (b) indicates the section number to be added to the text of the section indicated in column (a).

Subpart	(a) Section number to be added to section heading	(b) Section number to be added to text of the section in (a)
Subpart B—Corn dry milling subcategory.....	406.27	406.22
Subpart C—Normal wheat flour milling subcategory.....	406.37	406.32
Subpart D—Bulgur wheat flour milling subcategory.....	406.47	406.42
Subpart E—Normal rice milling subcategory.....	406.57	406.52
Subpart F—Parboiled rice processing subcategory.....	406.67	406.62
Subpart G—Animal feed subcategory.....	406.77	406.72
Subpart H—Hot cereal subcategory.....	406.87	406.82
Subpart I—Ready-to-eat cereal subcategory.....	406.97	406.92
Subpart J—Wheat starch and gluten.....	406.107	406.102

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § (b) of this subpart for the best practicable control technology currently available (BPT).

PART 407—CANNED AND PRESERVED FRUITS AND VEGETABLES PROCESSING POINT SOURCE CATEGORY

1. The authority citation for Part 407 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 407.17, 407.27, 407.47 [Revised]

§§ 407.37, 407.57, 407.67, 407.77, 407.87 [Added]

2. Sections 407.17, 407.27, and 407.47 are revised, and §§ 407.37, 407.57, 407.67, 407.77, and 407.87 are added. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 407. Column (b) indicates the section number to be added to the text of the section indicated in column (a).

Subpart	(a) Section number to be added to section heading	(b) Section number to be added to text of the section in (a)
Subpart A—Apple juice subcategory.....	407.17	407.12
Subpart B—Apple products subcategory.....	407.27	407.22
Subpart C—Citrus products subcategory.....	407.37	407.32
Subpart D—Frozen potato products subcategory.....	407.47	407.42
Subpart E—Dehydrated potato products subcategory.....	407.57	407.52

Subpart	(a) Section number to be added to section heading	(b) Section number to be added to text of the section in (a)
Subpart F—Canned and preserved fruits subcategory.....	407.67	407.62
Subpart G—Canned and preserved vegetable subcategory.....	407.77	407.72
Subpart H—Canned and miscellaneous specialties subcategory.....	407.87	407.82

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § (b) of this subpart for the best practicable control technology currently available (BPT).

PART 408—CANNED AND PRESERVED SEAFOOD PROCESSING POINT SOURCE CATEGORY

1. The authority citation for Part 408 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), 307(c), of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 408.17, 408.27, 408.37, 408.47, 408.57, 408.67, 408.77, 408.87, 408.97, 408.107, 408.117, 408.127, 408.137, 408.147, 408.157, 408.177, 408.187, 408.197, 408.217, 408.227, 408.237, 408.247, 408.277, 408.287, 408.317, 408.327 [Added]

2. Sections 408.17, 408.27, 408.37, 408.47, 408.57, 408.67, 408.77, 408.87, 408.97, 408.107, 408.117, 408.127, 408.137, 408.147, 408.157, 408.177, 408.187, 408.197, 408.217, 408.227, 408.237, 408.247, 408.277, 408.287, 408.317, and 408.327 are added. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 408. Column (b) indicates the section number

to be added to the text of the section indicated in column (a).

Subpart	(a) Section number to be added to section heading	(b) Section number to be added to text of the section in (a)
Subpart A—Farm-raised catfish processing subcategory.....	408.17	408.12
Subpart B—Conventional blue crab processing subcategory.....	408.27	408.22
Subpart C—Mechanized blue crab processing subcategory.....	408.37	408.32
Subpart D—Non-remote Alaskan crab meat processing subcategory.....	408.47	408.42
Subpart E—Remote Alaskan crab meat processing subcategory.....	408.57	408.52
Subpart F—Non-remote Alaskan whole crab and crab section processing subcategory.....	408.67	408.62
Subpart G—Remote Alaskan whole crab and crab section processing subcategory.....	408.77	408.72
Subpart H—Dungeness and Tanner crab processing in the contiguous states subcategory.....	408.87	408.82
Subpart I—Non-remote Alaskan shrimp processing subcategory.....	408.97	408.92
Subpart J—Remote Alaskan shrimp processing subcategory.....	408.107	408.102
Subpart K—Northern shrimp processing in the contiguous states subcategory.....	408.117	408.112
Subpart L—Southern non-breaded shrimp processing in the contiguous states subcategory.....	408.127	408.122
Subpart M—Breaded shrimp processing in the contiguous states subcategory.....	408.137	408.132
Subpart N—Tuna processing subcategory.....	408.147	408.142
Subpart O—Fish meal processing subcategory.....	408.157	408.152
Subpart Q—Alaskan mechanized salmon processing subcategory.....	408.177	408.172
Subpart R—West coast hand-buttered salmon processing subcategory.....	408.187	408.182
Subpart S—West coast mechanized salmon processing subcategory.....	408.197	408.192
Subpart U—Non-Alaskan conventional bottom fish processing subcategory.....	408.217	408.212
Subpart V—Non-Alaskan mechanized bottom fish processing subcategory.....	408.227	408.222
Subpart W—Hand-shucked clam processing subcategory.....	408.237	408.232
Subpart X—Mechanized clam processing subcategory.....	408.247	408.242
Subpart AA—Steamed and canned oyster processing subcategory.....	408.277	408.272
Subpart AB—Sardine processing subcategory.....	408.287	408.282
Subpart AE—Alaskan herring fillet processing subcategory.....	408.317	408.312
Subpart AF—Non-Alaskan herring fillet processing subcategory.....	408.327	408.322

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application

of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16 in § (b) of this subpart for the best practicable control technology currently available (BPT).

3. Section 408.167 is added to Subpart P to read as follows:

§ 408.167 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

(a) [Reserved].

(b) Except as provided in §§ 125.30 through 125.32, any hand-butchered salmon processing facility located in population or processing centers including but not limited to Anchorage, Cordova, Juneau, Ketchikan, Kodiak, and Petersburg shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § 408.162(b)(2) of this subpart for the best practicable control technology currently available (BPT).

4. Section 408.207 is added to Subpart T to read as follows:

§ 408.207 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

(a) [Reserved].

(b) Except as provided in §§ 125.30 through 125.32, any Alaskan bottom fish processing facility located in population or processing centers including but not limited to Anchorage, Cordova, Juneau, Ketchikan, Kodiak, and Petersburg shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § 408.202(b)(2) of this subpart for the best practicable control technology currently available (BPT).

5. Section 408.257 is added to Subpart Y to read as follows:

§ 408.257 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best conventional pollutant control technology:

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for thirty consecutive days shall not exceed—
Metric units (kilograms per 1,000 kg of product)		
TSS.....	45	36
Oil and grease.....	2.2	1.7
pH.....	(¹)	(¹)
English units (pounds per 1,000 lb of product)		
TSS.....	45	36
Oil and grease.....	2.2	1.7
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

6. Section 408.267 is added to Subpart Z to read as follows:

§ 408.267 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best conventional pollutant control technology:

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for thirty consecutive days shall not exceed—
Metric units (kilograms per 1,000 kg of product)		
TSS.....	23	16
Oil and grease.....	1.1	0.77
pH.....	(¹)	(¹)
English units (pounds per 1,000 lb of product)		
TSS.....	23	16
Oil and grease.....	1.1	0.77
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

7. Section 408.297 is added to Subpart AC to read as follows:

§ 408.297 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

(a) [Reserved].

(b) Except as provided in §§ 125.30 through 125.32, any Alaskan scallop processing facility located in population or processing centers including but not limited to Anchorage, Cordova, Juneau, Ketchikan, Kodiak, and Petersburg shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § 408.292(b)(2) of this subpart for the best practicable control technology currently available (BPT).

8. Section 408.307 is added to Subpart AD to read as follows:

§ 408.307 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best conventional pollutant control technology:

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for thirty consecutive days shall not exceed—
Metric units (kg/kg of product)		
TSS.....	5.7	1.4
Oil and grease.....	7.3	0.23
pH.....	(¹)	(¹)
English units (pounds per 1,000 lb of product)		
TSS.....	5.7	1.4
Oil and grease.....	7.3	0.23
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

9. Section 408.337 is added to Subpart AG to read as follows:

§ 408.337 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best conventional pollutant control technology:

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for thirty consecutive days shall not exceed

Metric units (kg/kg of seafood)		
TSS.....	26	14
Oil and grease.....	21	1.3
pH.....	(¹)	(¹)
English units (pounds per 1,000 lb of seafood)		
TSS.....	26	14
Oil and grease.....	2.1	1.3
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

PART 409—SUGAR PROCESSING POINT SOURCE CATEGORY

1. The authority citation for Part 409 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), 307 (c) and (d), and 316(b) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), 1317(c), and 1326(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 409.17, 409.27, 409.37 [Revised]

§§ 409.47, 409.57, 409.67, 409.77, 409.87 [Added]

2. Sections 409.17, 409.27, and 409.37 are revised, and §§ 409.47, 409.57, 409.67, 409.77, and 409.87 are added. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 409. Column (b) indicates the section number to be added to the text of the section indicated in column (a).

Subpart	(a)	(b)
	Section number to be added to section heading	Section number to be added to text of the section in (a)
Subpart A—Beet sugar processing subcategory.....	409.17	409.12
Subpart B—Crystalline cane sugar refining subcategory.....	409.27	409.22
Subpart C—Liquid cane sugar refining subcategory.....	409.37	409.32
Subpart D—Louisiana raw cane sugar processing subcategory.....	409.47	409.42
Subpart E—Florida and Texas raw cane sugar processing subcategory.....	409.57	409.52
Subpart F—Hilo-Hamaku Coast of the island of Hawaii raw cane sugar processing subcategory.....	409.67	409.62
Subpart G—Hawaiian raw cane sugar processing subcategory.....	409.77	409.72
Subpart H—Puerto Rican raw cane sugar processing subcategory.....	409.87	409.82

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § (b) of this subpart for the best practicable control technology currently available (BPT).

PART 411—CEMENT MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for Part 411 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), and 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), and 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

2. Section 411.27 is revised to read as follows:

§ 411.27 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The

limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § 411.22 of this subpart for the best practicable control technology currently available (BPT).

PART 412—FEEDLOTS POINT SOURCE CATEGORY

1. The authority citation for Part 412 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), and 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), and 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§ 412.17 [Removed and Reserved]

2. Section 412.17 is removed and reserved.

PART 418—FERTILIZER MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for Part 418 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), and 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

2. The heading of § 418.17 is revised to read as follows. (The entry for § 418.17 is also revised in the table of contents for Part 418.)

§ 418.17 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

* * * * *

3. In the table of contents for Part 418, the entry for § 418.27 is revised to read as follows:

Sec.	* * * * *
418.27	Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.
	* * * * *

4. Section 418.23 is revised to read as follows:

§ 418.23 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, which may be discharged by a point source

subject to the provisions of this subpart after application of the best available technology economically achievable.

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
Metric units (kilograms per 1,000 kg of product)		
Ammonia (as N).....	0.05	0.025
English units (pounds per 1,000 lb of product)		
Ammonia (as N).....	0.05	0.025

PART—422 PHOSPHATE MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for Part 422 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), and 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§ 422.66 [Revised]

- Section 422.66 is reserved.
- Section 422.67 is added to read as follows:

§ 422.67 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best conventional pollutant control technology:

[Metric units (kg/kg of product); English units (lb/1,000 lb of product)]

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
TSS.....	0.35	0.18
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.5.

PART 424—FERROALLOY MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for Part 424 is revised to read as follows:

Authority: Secs. 301, 304(b) and (c), 306(b) and (c), 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314(b) and (c), 1316 (b) and (c), 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 424.17, 424.27, 424.37 [Added]

§§ 424.47, 424.67, 424.77 [Revised]

2. Sections 424.17, 424.27, and 424.37 are added, and §§ 424.47, 424.67, and 424.77 are revised. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 424. Column (b) indicates the section number to be added to the text of the section indicated in column (a).

Subpart	(a) Section number to be added to section heading	(b) Section number to be added to text of the section in (a)
Subpart A—Open electric furnaces with wet air pollution control devices subcategory.....	424.17	424.12
Subpart B—Covered electric furnaces and other smelting operations with wet air pollution control devices subcategory.....	424.27	424.22
Subpart C—Slag processing subcategory.....	424.37	424.32
Subpart D—Covered calcium carbide furnaces with wet air pollution control devices subcategory.....	424.47	424.42
Subpart F—Electrolytic manganese products subcategory.....	424.67	424.62
Subpart G—Electrolytic chromium subcategory.....	424.77	424.72

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants

(which are defined in § 401.16) in § (b) of this subpart for the best practicable control technology currently available (BPT).

PART 426—GLASS MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for Part 426 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), 307(c), and 316(b) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314, 1316 (b) and (c), 1317(b); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 426.17 and 426.47 [Added]

§§ 426.57, 426.67, 426.77, 426.87, 426.107, 426.117, 426.127, 426.137 [Revised]

2. Sections 426.17 and 426.47 are added, and §§ 426.57, 426.67, 426.77, 426.87, 426.107, 426.117, 426.127, and 426.137 are revised. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 426. Column (b) indicates the section number to be added to the text of the section indicated in column (a).

Subpart	(a) Section number to be added to section heading	(b) Section number to be added to text of the section in (a)
Subpart A—Insulation fiberglass subcategory.....	426.17	426.12
Subpart D—Plate glass manufacturing subcategory.....	426.47	426.42
Subpart E—Float glass manufacturing subcategory.....	426.57	426.52
Subpart F—Automotive glass tempering subcategory.....	426.67	426.62
Subpart G—Automotive glass laminating subcategory.....		
Subpart H—Glass container manufacturing subcategory.....	426.87	426.82
Subpart J—Glass tubing (Danner) manufacturing subcategory.....	426.107	426.102
Subpart K—Television picture tube envelope manufacturing subcategory.....	426.117	426.112
Subpart L—Incandescent lamp envelope manufacturing subcategory.....	426.127	426.122

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source

subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § (b) of this subpart for the best practicable control technology currently available (BPT).

3. Section 426.123 is revised to read as follows:

§ 426.123 Effluent limitations guidelines representing the degree of effluent reduction available by the application of the best available technology economically achievable.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best available technology economically achievable:

(a) [Reserved]

(b) Any manufacturing plant which frosts incandescent lamp envelopes shall meet the following limitations with regard to the finishing operations.

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
Metric units (g/kg of product frosted)		
Fluoride.....	104.0	52.0
Ammonia.....	240.0	120.0
English units (lb/1,000 lb of product frosted)		
Fluoride.....	0.104	0.052
Ammonia.....	0.24	0.12

§ 426.133 [Amended]

4. In § 426.133, paragraph (c) is removed and reserved.

§ 426.137 [Removed and Reserved]

5. Section 426.137 is removed and reserved.

PART 432—MEAT PRODUCTS POINT SOURCE CATEGORY

1. The authority citation for Part 432 is revised to read as follows:

Authority: Secs. 301, 304 (b) and (c), 306 (b) and (c), and 307(c) of the Federal Water Pollution Control Act, as amended; 33 U.S.C. 1251, 1311, 1314 (b) and (c), 1316 (b) and (c), 1317(c); 86 Stat. 816 et seq., Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

§§ 432.17, 432.27, 432.37, 432.47, 432.67, 432.77, 432.87, 432.97 [Revised]

2. Sections 432.17, 432.27, 432.37, 432.47, 432.67, 432.77, 432.87, and 432.97 are revised. The text of each section is identical except for the section number in the heading and the section number referenced at the end of the section. The text of the sections is set out only once. Within the text are two blank spaces, one designated (a) and one designated (b). In the table preceding the text, column (a) indicates the section number to be added to the section heading for the respective subparts of Part 432. Column (b) indicates the section number to be added to the text of the section indicated in column (a).

Subpart	(a)	(b)
	Section number to be added to section heading	Section number to be added to text of the section in (a)
Subpart A—Simple slaughterhouse subcategory.....	432.17	432.12
Subpart B—Complex slaughterhouse subcategory.....	432.27	432.22
Subpart C—Low-processing packinghouse subcategory.....	432.37	432.32
Subpart D—High-processing packinghouse subcategory.....	432.47	432.42
Subpart F—Meat cutter subcategory.....	432.67	432.62
Subpart G—Sausage and luncheon meats processor subcategory.....	432.77	432.72
Subpart H—Ham processor subcategory.....	432.87	432.82
Subpart I—Canned meat processor subcategory.....	432.97	432.92

§ (a) Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants

(which are defined in § 401.16) in § (b) of this subpart for the best practicable control technology currently available (BPT).

3. Section 432.57 is added to Subpart E to read as follows:

§ 432.57 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

Except as provided in §§ 125.30 through 125.32, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best conventional pollutant control technology:

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
Metric units (kg/kg of finished product)		
BOD5.....	1.0	0.5
TSS.....	1.2	0.6
Oil and grease.....	0.5	0.25
pH.....	(¹)	(¹)
Fecal coliforms.....	(²)	(²)
English units (lb/1,000 lb of finished product)		
BOD5.....	1.0	0.5
TSS.....	1.2	0.6
Oil and grease.....	0.5	0.25
pH.....	(¹)	(¹)
* Fecal coliforms.....	(²)	(²)

¹ Within the range 6.0 to 9.0.

² No limitation.

4. Section 432.107 is added to Subpart J to read as follows:

§ 432.107 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology.

(a) Except as provided in §§ 125.30 through 125.32, and subject to the provisions of paragraph (b) of this section, the following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best conventional pollutant control technology:

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
Metric units (kg/kg of raw material)		
BOD5.....	0.18	0.09
TSS.....	0.22	0.11
Oil and grease.....	0.10	0.05
Fecal coliforms.....	(¹)	(¹)
pH.....	(²)	(²)
English units (lb/1,000 lb. of raw material)		
BOD5.....	0.18	0.09
TSS.....	0.22	0.11
Oil and grease.....	0.10	0.05
Fecal coliforms.....	(¹)	(¹)
pH.....	(²)	(²)

¹ Maximum at any time: 400 mpn/100 ml.² Within the range 6.0 to 9.0.

(b) The limitations given in paragraph (a) of this section for BOD5 and TSS are derived for a renderer which does no cattle hide curing as part of the plant activities. If a renderer does conduct hide curing, the following empirical formulas should be used to derive an additive adjustment to the effluent limitations for BOD5 and TSS.

BOD5 Adjustment (kg/kg RM) = $3.6 \times (\text{number of hides}) / \text{kg of raw material}$

(lb/1,000 lb RM) = $7.9 \times (\text{number of hides}) / \text{lbs of raw material}$

TSS Adjustment (kg/kg RM) = $6.2 \times (\text{number of hides}) / \text{kg of raw material}$

(lb/1,000 lb RM) = $13.6 \times (\text{number of hides}) / \text{lbs of raw material}$

[FR Doc. 86-11789 Filed 7-8-86; 8:45 am]

BILLING CODE 6560-50-M

Environmental Protection Agency

Wednesday
July 9, 1986

Part IV

Environmental Protection Agency

Environmental Auditing Policy Statement;
Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPPE-FRL-3046-6]

Environmental Auditing Policy Statement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final policy statement.

SUMMARY: It is EPA policy to encourage the use of environmental auditing by regulated entities to help achieve and maintain compliance with environmental laws and regulations, as well as to help identify and correct unregulated environmental hazards. EPA first published this policy as interim guidance on November 8, 1985 (50 FR 46504). Based on comments received regarding the interim guidance, the Agency is issuing today's final policy statement with only minor changes.

This final policy statement specifically:

- Encourages regulated entities to develop, implement and upgrade environmental auditing programs;
- Discusses when the Agency may or may not request audit reports;
- Explains how EPA's inspection and enforcement activities may respond to regulated entities' efforts to assure compliance through auditing;
- Endorses environmental auditing at federal facilities;
- Encourages state and local environmental auditing initiatives; and
- Outlines elements of effective audit programs.

Environmental auditing includes a variety of compliance assessment techniques which go beyond those legally required and are used to identify actual and potential environmental problems. Effective environmental auditing can lead to higher levels of overall compliance and reduced risk to human health and the environment. EPA endorses the practice of environmental auditing and supports its accelerated use by regulated entities to help meet the goals of federal, state and local environmental requirements. However, the existence of an auditing program does not create any defense to, or otherwise limit, the responsibility of any regulated entity to comply with applicable regulatory requirements.

States are encouraged to adopt these or similar and equally effective policies in order to advance the use of environmental auditing on a consistent, nationwide basis.

DATES: This final policy statement is effective July 9, 1986.

FOR FURTHER INFORMATION CONTACT:

Leonard Fleckenstein, Office of Policy, Planning and Evaluation, (202) 382-2726;

or

Cheryl Wasserman, Office of Enforcement and Compliance Monitoring, (202) 382-7550.

SUPPLEMENTARY INFORMATION:

ENVIRONMENTAL AUDITING POLICY STATEMENT

I. Preamble

On November 8, 1985 EPA published an Environmental Auditing Policy Statement, effective as interim guidance, and solicited written comments until January 7, 1986.

Thirteen commenters submitted written comments. Eight were from private industry. Two commenters represented industry trade associations. One federal agency, one consulting firm and one law firm also submitted comments.

Twelve commenters addressed EPA requests for audit reports. Three comments per subject were received regarding inspections, enforcement response and elements of effective environmental auditing. One commenter addressed audit provisions as remedies in enforcement actions, one addressed environmental auditing at federal facilities, and one addressed the relationship of the policy statement to state or local regulatory agencies. Comments generally supported both the concept of a policy statement and the interim guidance, but raised specific concerns with respect to particular language and policy issues in sections of the guidance.

General Comments

Three commenters found the interim guidance to be constructive, balanced and effective at encouraging more and better environmental auditing.

Another commenter, while considering the policy on the whole to be constructive, felt that new and identifiable auditing "incentives" should be offered by EPA. Based on earlier comments received from industry, EPA believes most companies would not support or participate in an "incentives-based" environmental auditing program with EPA. Moreover, general promises to forgo inspections or reduce enforcement responses in exchange for companies' adoption of environmental auditing programs—the "incentives" most frequently mentioned in this context—are fraught with legal and policy obstacles.

Several commenters expressed concern that states or localities might

use the interim guidance to *require* auditing. The Agency disagrees that the policy statement opens the way for states and localities to require auditing. No EPA policy can grant states or localities any more (or less) authority than they already possess. EPA believes that the interim guidance effectively encourages *voluntary* auditing. In fact, Section II.B. of the policy states: "because audit quality depends to a large degree on genuine management commitment to the program and its objectives, auditing should remain a voluntary program."

Another commenter suggested that EPA should not expect an audit to identify all potential problem areas or conclude that a problem identified in an audit reflects normal operations and procedures. EPA agrees that an audit report should clearly reflect these realities and should be written to point out the audit's limitations. However, since EPA will not routinely request audit reports, the Agency does not believe these concerns raise issues which need to be addressed in the policy statement.

A second concern expressed by the same commenter was that EPA should acknowledge that environmental audits are only part of a successful environmental management program and thus should not be expected to cover every environmental issue or solve all problems. EPA agrees and accordingly has amended the statement of purpose which appears at the end of this preamble.

Yet another commenter thought EPA should focus on environmental performance results (compliance or non-compliance), not on the processes or vehicles used to achieve those results. In general, EPA agrees with this statement and will continue to focus on environmental results. However, EPA also believes that such results can be improved through Agency efforts to identify and encourage effective environmental management practices, and will continue to encourage such practices in non-regulatory ways.

A final general comment recommended that EPA should sponsor seminars for small businesses on how to start auditing programs. EPA agrees that such seminars would be useful. However, since audit seminars already are available from several private sector organizations, EPA does not believe it should intervene in that market, with the possible exception of seminars for government agencies, especially federal agencies, for which EPA has a broad mandate under Executive Order 12088 to

provide technical assistance for environmental compliance.

Requests for Reports

EPA received 12 comments regarding Agency requests for environmental audit reports, far more than on any other topic in the policy statement. One commenter felt that EPA struck an appropriate balance between respecting the need for self-evaluation with some measure of privacy, and allowing the Agency enough flexibility of inquiry to accomplish future statutory missions. However, most commenters expressed concern that the interim guidance did not go far enough to assuage corporate fears that EPA will use audit reports for environmental compliance "witch hunts." Several commenters suggested additional specific assurances regarding the circumstances under which EPA will request such reports.

One commenter recommended that EPA request audit reports only "when the Agency can show the information it needs to perform its statutory mission cannot be obtained from the monitoring, compliance or other data that is otherwise reportable and/or accessible to EPA, or where the Government deems an audit report material to a criminal investigation." EPA accepts this recommendation in part. The Agency believes it would not be in the best interest of human health and the environment to commit to making a "showing" of a compelling information need before ever requesting an audit report. While EPA may normally be willing to do so, the Agency cannot rule out in advance all circumstances in which such a showing may not be possible. However, it would be helpful to further clarify that a request for an audit report or a portion of a report normally will be made when needed information is not available by alternative means. Therefore, EPA has revised Section III.A., paragraph two and added the phrase: "and usually made where the information needed cannot be obtained from monitoring, reporting or other data otherwise available to the Agency."

Another commenter suggested that (except in the case of criminal investigations) EPA should limit requests for audit documents to specific questions. By including the phrase "or relevant portions of a report" in Section III.A., EPA meant to emphasize it would not request an entire audit document when only a relevant portion would suffice. Likewise, EPA fully intends not to request even a portion of a report if needed information or data can be otherwise obtained. To further clarify this point EPA has added the phrase,

"most likely focused on particular information needs rather than the entire report," to the second sentence of paragraph two, Section III.A. Incorporating the two comments above, the first two sentences in paragraph two of final Section III.A. now read: "EPA's authority to request an audit report, or relevant portions thereof, will be exercised on a case-by-case basis where the Agency determines it is needed to accomplish a statutory mission or the Government deems it to be material to a criminal investigation. EPA expects such requests to be limited, most likely focused on particular information needs rather than the entire report, and usually made where the information needed cannot be obtained from monitoring, reporting or other data otherwise available to the Agency."

Other commenters recommended that EPA not request audit reports under any circumstances, that requests be "restricted to only those legally required," that requests be limited to criminal investigations, or that requests be made only when EPA has reason to believe "that the audit programs or reports are being used to conceal evidence of environmental non-compliance or otherwise being used in bad faith." EPA appreciates concerns underlying all of these comments and has considered each carefully. However, the Agency believes that these recommendations do not strike the appropriate balance between retaining the flexibility to accomplish EPA's statutory missions in future, unforeseen circumstances, and acknowledging regulated entities' need to self-evaluate environmental performance with some measure of privacy. Indeed, based on prime informal comments, the small number of formal comments received, and the even smaller number of adverse comments, EPA believes the final policy statement should remain largely unchanged from the interim version.

Elements of Effective Environmental Auditing

Three commenters expressed concerns regarding the seven general elements EPA outlined in the Appendix to the interim guidance.

One commenter noted that were EPA to further expand or more fully detail such elements, programs not specifically fulfilling each element would then be judged inadequate. EPA agrees that presenting highly specific and prescriptive auditing elements could be counter-productive by not taking into account numerous factors which vary extensively from one organization to another, but which may still result in effective auditing programs.

Accordingly, EPA does not plan to expand or more fully detail these auditing elements.

Another commenter asserted that states and localities should be cautioned not to consider EPA's auditing elements as mandatory steps. The Agency is fully aware of this concern and in the interim guidance noted its strong opinion that "regulatory agencies should not attempt to prescribe the precise form and structure of regulated entities' environmental management or auditing programs." While EPA cannot require state or local regulators to adopt this or similar policies, the Agency does strongly encourage them to do so, both in the interim and final policies.

A final commenter thought the Appendix too specifically prescribed what should and what should not be included in an auditing program. Other commenters, on the other hand, viewed the elements described as very general in nature. EPA agrees with these other commenters. The elements are in no way binding. Moreover, EPA believes that most mature, effective environmental auditing programs do incorporate each of these general elements in some form, and considers them useful yardsticks for those considering adopting or upgrading audit programs. For these reasons EPA has not revised the Appendix in today's final policy statement.

Other Comments

Other significant comments addressed EPA inspection priorities for, and enforcement responses to, organizations with environmental auditing programs.

One commenter, stressing that audit programs are *internal* management tools, took exception to the phrase in the second paragraph of section III.B.1. of the interim guidance which states that environmental audits can 'complement' regulatory oversight. By using the word 'complement' in this context, EPA does not intend to imply that audit reports must be obtained by the Agency in order to supplement regulatory inspections. 'Complement' is used in a broad sense of being in addition to inspections and providing something (i.e., self-assessment) which otherwise would be lacking. To clarify this point EPA has added the phrase "by providing self-assessment to assure compliance" after "environmental audits may complement inspections" in this paragraph.

The same commenter also expressed concern that, as EPA sets inspection priorities, a company having an audit program could appear to be a 'poor performer' due to complete and accurate reporting when measured against a

company which reports something less than required by law. EPA agrees that it is important to communicate this fact to Agency and state personnel, and will do so. However, the Agency does not believe a change in the policy statement is necessary.

A further comment suggested EPA should commit to take auditing programs into account when assessing all enforcement actions. However, in order to maintain enforcement flexibility under varied circumstances, the Agency cannot promise reduced enforcement responses to violations at all audited facilities when other factors may be overriding. Therefore the policy statement continues to state that EPA may exercise its discretion to consider auditing programs as evidence of honest and genuine efforts to assure compliance, which would then be taken into account in fashioning enforcement responses to violations.

A final commenter suggested the phrase "expeditiously correct environmental problems" not be used in the enforcement context since it implied EPA would use an entity's record of correcting nonregulated matters when evaluating regulatory violations. EPA did not intend for such an inference to be made. EPA intended the term "environmental problems" to refer to the underlying circumstances which eventually lead up to the violations. To clarify this point, EPA is revising the first two sentences of the paragraph to which this comment refers by changing "environmental problems" to "violations and underlying environmental problems" in the first sentence and to "underlying environmental problems" in the second sentence.

In a separate development EPA is preparing an update of its January 1984 *Federal Facilities Compliance Strategy*, which is referenced in section III. C. of the auditing policy. The Strategy should be completed and available on request from EPA's Office of Federal Activities later this year.

EPA thanks all commenters for responding to the November 8, 1985 publication. Today's notice is being issued to inform regulated entities and the public of EPA's final policy toward environmental auditing. This policy was developed to help (a) encourage regulated entities to institutionalize effective audit practices as one means of improving compliance and sound environmental management, and (b) guide internal EPA actions directly related to regulated entities' environmental auditing programs.

EPA will evaluate implementation of this final policy to ensure it meets the above goals and continues to encourage

better environmental management, while strengthening the Agency's own efforts to monitor and enforce compliance with environmental requirements.

II. General EPA Policy on Environmental Auditing

A. Introduction

Environmental auditing is a systematic, documented, periodic and objective review by regulated entities¹ of facility operations and practices related to meeting environmental requirements. Audits can be designed to accomplish any or all of the following: verify compliance with environmental requirements; evaluate the effectiveness of environmental management systems already in place; or assess risks from regulated and unregulated materials and practices.

Auditing serves as a quality assurance check to help improve the effectiveness of basic environmental management by verifying that management practices are in place, functioning and adequate. Environmental audits evaluate, and are not a substitute for, direct compliance activities such as obtaining permits, installing controls, monitoring compliance, reporting violations, and keeping records. Environmental auditing may verify but does not include activities required by law, regulation or permit (e.g., continuous emissions monitoring, composite correction plans at wastewater treatment plants, etc.). Audits do not in any way replace regulatory agency inspections. However, environmental audits can improve compliance by complementing conventional federal, state and local oversight.

The appendix to this policy statement outlines some basic elements of environmental auditing (e.g., auditor independence and top management support) for use by those considering implementation of effective auditing programs to help achieve and maintain compliance. Additional information on environmental auditing practices can be found in various published materials.²

¹ "Regulated entities" include private firms and public agencies with facilities subject to environmental regulation. Public agencies can include federal, state or local agencies as well as special-purpose organizations such as regional sewage commissions.

² See, e.g., "Current Practices in Environmental Auditing," EPA Report No. EPA-230-09-83-006, February 1984; "Annotated Bibliography on Environmental Auditing," Fifth Edition, September 1985, both available from: Regulatory Reform Staff, PM-223, EPA, 401 M Street SW, Washington, DC 20460.

Environmental auditing has developed for sound business reasons, particularly as a means of helping regulated entities manage pollution control affirmatively over time instead of reacting to crises. Auditing can result in improved facility environmental performance, help communicate effective solutions to common environmental problems, focus facility managers' attention on current and upcoming regulatory requirements, and generate protocols and checklists which help facilities better manage themselves. Auditing also can result in better-integrated management of environmental hazards, since auditors frequently identify environmental liabilities which go beyond regulatory compliance. Companies, public entities and federal facilities have employed a variety of environmental auditing practices in recent years. Several hundred major firms in diverse industries now have environmental auditing programs, although they often are known by other names such as assessment, survey, surveillance, review or appraisal.

While auditing has demonstrated its usefulness to those with audit programs, many others still do not audit. Clarification of EPA's position regarding auditing may help encourage regulated entities to establish audit programs or upgrade systems already in place.

B. EPA Encourages the Use of Environmental Auditing

EPA encourages regulated entities to adopt sound environmental management practices to improve environmental performance. In particular, EPA encourages regulated entities subject to environmental regulations to institute environmental auditing programs to help ensure the adequacy of internal systems to achieve, maintain and monitor compliance. Implementation of environmental auditing programs can result in better identification, resolution and avoidance of environmental problems, as well as improvements to management practices. Audits can be conducted effectively by independent internal or third party auditors. Larger organizations generally have greater resources to devote to an internal audit team, while smaller entities might be more likely to use outside auditors.

Regulated entities are responsible for taking all necessary steps to ensure compliance with environmental requirements, whether or not they adopt audit programs. Although environmental laws do not require a regulated facility to have an auditing program, ultimate responsibility for the environmental

performance of the facility lies with top management, which therefore has a strong incentive to use reasonable means, such as environmental auditing, to secure reliable information of facility compliance status.

EPA does not intend to dictate or interfere with the environmental management practices of private or public organizations. Nor does EPA intend to mandate auditing (though in certain instances EPA may seek to include provisions for environmental auditing as part of settlement agreements, as noted below). Because environmental auditing systems have been widely adopted on a voluntary basis in the past, and because audit quality depends to a large degree upon genuine management commitment to the program and its objectives, auditing should remain a voluntary activity.

III. EPA Policy on Specific Environmental Auditing Issues

A. Agency Requests for Audit Reports

EPA has broad statutory authority to request relevant information on the environmental compliance status of regulated entities. However, EPA believes routine Agency requests for audit reports³ could inhibit auditing in the long run, decreasing both the quantity and quality of audits conducted. Therefore, as a matter of policy, EPA will *not* routinely request environmental audit reports.

EPA's authority to request an audit report, or relevant portions thereof, will be exercised on a case-by-case basis where the Agency determines it is needed to accomplish a statutory mission, or where the Government deems it to be material to a criminal investigation. EPA expects such requests to be limited, most likely focused on particular information needs rather than the entire report, and usually made where the information needed cannot be obtained from monitoring, reporting or other data otherwise available to the Agency. Examples would likely include situations where: audits are conducted under consent decrees or other settlement agreements; a company has placed its management practices at issue by raising them as a defense; or state of mind or intent are a relevant element of inquiry, such as during a criminal investigation. This list

is illustrative rather than exhaustive, since there doubtless will be other situations, not subject to prediction, in which audit reports rather than information may be required.

EPA acknowledges regulated entities' need to self-evaluate environmental performance with some measure of privacy and encourages such activity. However, audit reports may not shield monitoring, compliance, or other information that would otherwise be reportable and/or accessible to EPA, even if there is no explicit 'requirement' to generate that data.⁴ Thus, this policy does not alter regulated entities' existing or future obligations to monitor, record or report information required under environmental statutes, regulations or permits, or to allow EPA access to that information. Nor does this policy alter EPA's authority to request and receive any relevant information—including that contained in audit reports—under various environmental statutes (e.g., Clean Water Act section 308, Clean Air Act sections 114 and 208) or in other administrative or judicial proceedings.

Regulated entities also should be aware that certain audit findings may by law have to be reported to government agencies. However, in addition to any such requirements, EPA encourages regulated entities to notify appropriate State or Federal officials of findings which suggest significant environmental or public health risks, even when not specifically required to do so.

B. EPA Response to Environmental Auditing

1. General Policy

EPA will not promise to forgo inspections, reduce enforcement responses, or offer other such incentives in exchange for implementation of environmental auditing or other sound environmental management practices. Indeed, a credible enforcement program provides a strong incentive for regulated entities to audit.

Regulatory agencies have an obligation to assess source compliance status independently and cannot eliminate inspections for particular firms or classes of firms. Although environmental audits may complement inspections by providing self-assessment to assure compliance, they are in no way a substitute for regulatory oversight. Moreover, certain statutes (e.g. RCRA) and Agency policies

establish minimum facility inspection frequencies to which EPA will adhere.

However, EPA will continue to address environmental problems on a priority basis and will consequently inspect facilities with poor environmental records and practices more frequently. Since effective environmental auditing helps management identify and promptly correct actual or potential problems, audited facilities' environmental performance should improve. Thus, while EPA inspections of self-audited facilities will continue, to the extent that compliance performance is considered in setting inspection priorities, facilities with a good compliance history may be subject to fewer inspections.

In fashioning enforcement responses to violations, EPA policy is to take into account, on a case-by-case basis, the honest and genuine efforts of regulated entities to avoid and promptly correct violations and underlying environmental problems. When regulated entities take reasonable precautions to avoid noncompliance, expeditiously correct underlying environmental problems discovered through audits or other means, and implement measures to prevent their recurrence, EPA may exercise its discretion to consider such actions as honest and genuine efforts to assure compliance. Such consideration applies particularly when a regulated entity promptly reports violations or compliance data which otherwise were not required to be recorded or reported to EPA.

2. Audit Provisions as Remedies in Enforcement Actions

EPA may propose environmental auditing provisions in consent decrees and in other settlement negotiations where auditing could provide a remedy for identified problems and reduce the likelihood of similar problems recurring in the future.⁵ Environmental auditing provisions are most likely to be proposed in settlement negotiations where:

- A pattern of violations can be attributed, at least in part, to the absence or poor functioning of an environmental management system; or
- The type or nature of violations indicates a likelihood that similar noncompliance problems may exist or occur elsewhere in the facility or at other facilities operated by the regulated entity.

³ An "environmental audit report" is a written report which candidly and thoroughly presents findings from a review, conducted as part of an environmental audit as described in section II.A., of facility environmental performance and practices. An audit report is not a substitute for compliance monitoring reports or other reports or records which may be required by EPA or other regulatory agencies.

⁴ See, for example, "Duties to Report or Disclose Information on the Environmental Aspects of Business Activities," Environmental Law Institute report to EPA, final report, September 1985.

⁵ EPA is developing guidance for use by Agency negotiators in structuring appropriate environmental audit provisions for consent decrees and other settlement negotiations.

Through this consent decree approach and other means, EPA may consider how to encourage effective auditing by publicly owned sewage treatment works (POTWs). POTWs often have compliance problems related to operation and maintenance procedures which can be addressed effectively through the use of environmental auditing. Under its National Municipal Policy EPA already is requiring many POTWs to develop composite correction plans to identify and correct compliance problems.

C. Environmental Auditing at Federal Facilities

EPA encourages all federal agencies subject to environmental laws and regulations to institute environmental auditing systems to help ensure the adequacy of internal systems to achieve, maintain and monitor compliance. Environmental auditing at federal facilities can be an effective supplement to EPA and state inspections. Such federal facility environmental audit programs should be structured to promptly identify environmental problems and expeditiously develop schedules for remedial action.

To the extent feasible, EPA will provide technical assistance to help federal agencies design and initiate audit programs. Where appropriate, EPA will enter into agreements with other agencies to clarify the respective roles, responsibilities and commitments of each agency in conducting and responding to federal facility environmental audits.

With respect to inspections of self-audited facilities (see section III.B.1 above) and requests for audit reports (see section III.A above), EPA generally will respond to environmental audits by federal facilities in the same manner as it does for other regulated entities, in keeping with the spirit and intent of Executive Order 12088 and the EPA *Federal Facilities Compliance Strategy* (January 1984, update forthcoming in late 1986). Federal agencies should, however, be aware that the Freedom of Information Act will govern any disclosure of audit reports or audit-generated information requested from federal agencies by the public.

When federal agencies discover significant violations through an environmental audit, EPA encourages them to submit the related audit findings and remedial action plans expeditiously to the applicable EPA regional office (and responsible state agencies, where appropriate) even when not specifically required to do so. EPA will review the audit findings and action plans and either provide written approval or

negotiate a Federal Facilities Compliance Agreement. EPA will utilize the escalation procedures provided in Executive Order 12088 and the EPA *Federal Facilities Compliance Strategy* only when agreement between agencies cannot be reached. In any event, federal agencies are expected to report pollution abatement projects involving costs (necessary to correct problems discovered through the audit) to EPA in accordance with OMB Circular A-106. Upon request, and in appropriate circumstances, EPA will assist affected federal agencies through coordination of any public release of audit findings with approved action plans once agreement has been reached.

IV. Relationship to State or Local Regulatory Agencies

State and local regulatory agencies have independent jurisdiction over regulated entities. EPA encourages them to adopt these or similar policies, in order to advance the use of effective environmental auditing in a consistent manner.

EPA recognizes that some states have already undertaken environmental auditing initiatives which differ somewhat from this policy. Other states also may want to develop auditing policies which accommodate their particular needs or circumstances. Nothing in this policy statement is intended to preempt or preclude states from developing other approaches to environmental auditing. EPA encourages state and local authorities to consider the basic principles which guided the Agency in developing this policy:

- Regulated entities must continue to report or record compliance information required under existing statutes or regulations, regardless of whether such information is generated by an environmental audit or contained in an audit report. Required information cannot be withheld merely because it is generated by an audit rather than by some other means.

- Regulatory agencies cannot make promises to forgo or limit enforcement action against a particular facility or class of facilities in exchange for the use of environmental auditing systems. However, such agencies may use their discretion to adjust enforcement actions on a case-by-case basis in response to honest and genuine efforts by regulated entities to assure environmental compliance.

- When setting inspection priorities regulatory agencies should focus to the extent possible on compliance performance and environmental results.

- Regulatory agencies must continue to meet minimum program requirements

(e.g., minimum inspection requirements, etc.).

- Regulatory agencies should not attempt to prescribe the precise form and structure of regulated entities' environmental management or auditing programs.

An effective state/federal partnership is needed to accomplish the mutual goal of achieving and maintaining high levels of compliance with environmental laws and regulations. The greater the consistency between state or local policies and this federal response to environmental auditing, the greater the degree to which sound auditing practices might be adopted and compliance levels improve.

Dated: June 28, 1986.

Lee M. Thomas,
Administrator.

Appendix—Elements of Effective Environmental Auditing Programs

Introduction: Environmental auditing is a systematic, documented, periodic and objective review by a regulated entity of facility operations and practices related to meeting environmental requirements.

Private sector environmental audits of facilities have been conducted for several years and have taken a variety of forms, in part to accommodate unique organizational structures and circumstances. Nevertheless, effective environmental audits appear to have certain discernible elements in common with other kinds of audits. Standards for internal audits have been documented extensively. The elements outlined below draw heavily on two of these documents: "Compendium of Audit Standards" (*1983, Walter Willborn, American Society for Quality Control) and "Standards for the Professional Practice of Internal Auditing" (*1981, The Institute of Internal Auditors, Inc.). They also reflect Agency analyses conducted over the last several years.

Performance-oriented auditing elements are outlined here to help accomplish several objectives. A general description of features of effective, mature audit programs can help those starting audit programs, especially federal agencies and smaller businesses. These elements also indicate the attributes of auditing EPA generally considers important to ensure program effectiveness. Regulatory agencies may use these elements in negotiating environmental auditing provisions for consent decrees. Finally, these elements can help guide states and localities considering auditing initiatives.

An effective environmental auditing system will likely include the following general elements:

I. Explicit top management support for environmental auditing and commitment to follow-up on audit findings. Management support may be demonstrated by a written policy articulating upper management support for the auditing program, and for compliance with all pertinent requirements, including corporate policies and permit requirements as well as federal, state and local statutes and regulations.

Management support for the auditing program also should be demonstrated by an explicit written commitment to follow-up on audit findings to correct identified problems and prevent their recurrence.

II. An environmental auditing function independent of audited activities. The status or organizational locus of environmental auditors should be sufficient to ensure objective and unobstructed inquiry, observation and testing. Auditor objectivity should not be impaired by personal relationships, financial or other conflicts of interest, interference with free inquiry or judgment, or fear of potential retribution.

III. Adequate team staffing and auditor training. Environmental auditors should possess or have ready access to the knowledge, skills, and disciplines needed to accomplish audit objectives. Each individual auditor should comply with the company's professional standards of conduct. Auditors, whether full-time or part-time, should maintain their technical and analytical competence through continuing education and training.

IV. Explicit audit program objectives, scope, resources and frequency. At a minimum, audit objectives should include assessing compliance with applicable environmental laws and evaluating the adequacy of internal compliance policies, procedures and personnel training programs to ensure continued compliance.

Audits should be based on a process which provides auditors: all corporate policies, permits, and federal, state, and local regulations pertinent to the facility; and checklists or protocols addressing specific features that should be evaluated by auditors.

Explicit written audit procedures generally should be used for planning audits, establishing audit scope, examining and evaluating audit findings, communicating audit results, and following-up.

V. A process which collects, analyzes, interprets and documents information sufficient to achieve audit objectives. Information should be collected before and during an onsite visit regarding environmental compliance(1), environmental management effectiveness(2), and other matters (3) related to audit objectives and scope. This information should be sufficient, reliable, relevant and useful to provide a sound basis for audit findings and recommendations.

a. *Sufficient* information is factual, adequate and convincing so that a prudent, informed person would be likely to reach the same conclusions as the auditor.

b. *Reliable* information is the best attainable through use of appropriate audit techniques.

c. *Relevant* information supports audit findings and recommendations and is consistent with the objectives for the audit.

d. *Useful* information helps the organization meet its goals.

The audit process should include a periodic review of the reliability and integrity of this information and the means used to identify, measure, classify and report it. Audit procedures, including the testing and sampling techniques employed, should be selected in advance, to the extent practical, and expanded or altered if circumstances warrant. The process of collecting, analyzing, interpreting, and documenting information should provide reasonable assurance that audit objectivity is maintained and audit goals are met.

VI. A process which includes specific procedures to promptly prepare candid, clear and appropriate written reports on audit findings, corrective actions, and schedules for implementation.

Procedures should be in place to ensure that such information is communicated to managers, including facility and corporate management, who can evaluate the information and ensure correction of identified problems. Procedures also should be in place for determining what internal findings are reportable to state or federal agencies.

VII. A process which includes quality assurance procedures to assure the accuracy and thoroughness of environmental audits. Quality assurance may be accomplished through supervision, independent internal reviews, external reviews, or a combination of these approaches.

Footnotes to Appendix

(1) A comprehensive assessment of compliance with federal environmental regulations requires an analysis of facility performance against numerous environmental statutes and implementing regulations. These statutes include: Resource Conservation and Recovery Act, Federal Water Pollution Control Act, Clean Air Act, Hazardous Materials Transportation Act, Toxic Substances Control Act, Comprehensive Environmental Response, Compensation and Liability Act, Safe Drinking Water Act, Federal Insecticide, Fungicide and Rodenticide Act, Marine Protection, Research and Sanctuaries Act, Uranium Mill Tailings Radiation Control Act.

In addition, state and local government are likely to have their own environmental laws. Many states have been delegated authority to administer federal programs. Many local governments' building, fire, safety and health codes also have environmental requirements relevant to an audit evaluation.

(2) An environmental audit could go well beyond the type of compliance assessment normally conducted during regulatory inspections, for example, by evaluating policies and practices, regardless of whether they are part of the environmental system or the operating and maintenance procedures. Specifically, audits can evaluate the extent to which systems or procedures:

1. Develop organizational environmental policies which: a. implement regulatory requirements; b. provide management guidance for environmental hazards not specifically addressed in regulations;

2. Train and motivate facility personnel to work in an environmentally-acceptable manner and to understand and comply with government regulations and the entity's environmental policy;

3. Communicate relevant environmental developments expeditiously to facility and other personnel;

4. Communicate effectively with government and the public regarding serious environmental incidents;

5. Require third parties working for, with or on behalf of the organization to follow its environmental procedures;

6. Make proficient personnel available at all times to carry out environmental (especially emergency) procedures;
7. Incorporate environmental protection into written operating procedures;
8. Apply best management practices and operating procedures, including "good housekeeping" techniques;
9. Institute preventive and corrective maintenance systems to minimize actual and potential environmental harm;
10. Utilize best available process and control technologies;
11. Use most-effective sampling and monitoring techniques, test methods, recordkeeping systems or reporting protocols (beyond minimum legal requirements);
12. Evaluate causes behind any serious environmental incidents and establish procedures to avoid recurrence;
13. Exploit source reduction, recycle and reuse potential wherever practical; and
14. Substitute materials or processes to allow use of the least-hazardous substances feasible.

(3) Auditors could also assess environmental risks and uncertainties.

[FR Doc. 86-15423 Filed 7-8-86 8:45 am]

BILLING CODE 6560-50-M

Wednesday
July 9, 1986

Part V

**Department of
Health and Human
Services**

Food and Drug Administration

21 CFR Part 101

**Food Labeling; Declaration of Sulfiting
Agents; Final Rule**

21 CFR Part 182

**Sulfiting Agents; Revocation of GRAS
Status for Use on Fruits and Vegetables
Intended To Be Served or Sold Raw to
Consumers; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 84N-0103]

Food Labeling; Declaration of Sulfiting Agents

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting a regulation that clarifies the circumstances in which the presence of sulfiting agents (also referred to as "sulfites") must be declared on the label of foods. This regulation makes clear that when a sulfite is present in a detectable amount in a finished food, regardless of whether it has been directly added or indirectly added via one or more of the ingredients of the food, it is present in that food at a significant level and must be declared on the label. The regulation defines a detectable amount of sulfite to be 10 parts per million.

DATES: Effective January 9, 1987. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 101.100 effective on January 9, 1987.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0175.

SUPPLEMENTARY INFORMATION:**Background**

Under section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)(2)), all of the ingredients of a finished food must be declared on the label of that food. However, that section also provides that exemptions from this requirement may be established when compliance with it is impracticable. Therefore, in 21 CFR 101.100(a)(3), FDA has created an exemption from that requirement for incidental additives. Under § 101.100(a)(3), an "incidental additive" is defined as an ingredient that has no technical or functional effect in the finished food and that is present in that food at a level that is insignificant.

FDA determines whether a substance exerts a technical or functional effect in a food on a case-by-case basis, because the factors influencing that determination will vary from food to food. FDA advises that food

manufacturers who claim that a substance is an incidental additive have the burden of showing that the substance has no technical or functional effect in the food. If the ingredient is added directly to the food for a technical or functional effect, it must be declared on the label irrespective of the amount present in the finished food.

The present action, however, relates to the second part of the definition of "incidental additives." Its purpose is to define the level of sulfiting agents that is significant.

The sulfiting agents are sulfur dioxide, sodium sulfite, and sodium or potassium bisulfite or metabisulfite. In the *Federal Register* of April 3, 1985 (50 FR 13306), FDA proposed to establish 10 parts per million (ppm) as the level of sulfiting agent that the agency considers to be significant for purposes of labeling.

FDA received 53 comments in response to that proposal from consumers, food manufacturers and processors, trade associations, health-oriented associations, members of Congress, a research institute, a consumer interest organization, a State agency, and a county agency. Most of the comments supported the concept of requiring declaration of sulfites. A number of the comments were from consumers who said they were sensitive to sulfites and wanted FDA to take even stronger measures. A number of the comments from industry, however, requested revisions of the proposed provision that would limit the circumstances in which sulfite declarations would be required. The issues raised in the comments and the agency's responses follow.

Terminology

Before addressing the specific comments, it may be helpful to the reader to explain some of the terminology used in this document.

A broad chemical definition of "sulfite" is a salt or ester of sulfurous acid. This term has become widely used in a nontechnical sense to refer to some or all of the sulfiting agents. However, it is also used generically to refer to the collection of chemical species that are formed when sulfiting agents are added to foods.

When a sulfiting agent is added to a food, some of this ingredient binds to the molecules of the food and some of it does not. The portion of the sulfiting agent that does not bind to the food is called "free sulfite." "Free sulfite" is a mixture of sulfur dioxide, bisulfite ion, and sulfite ion in dynamic chemical equilibrium. The percentage of each of the three chemical species in the

mixture is dependent upon the acidity of the food.

"Bound sulfite" refers to the variety of chemical species formed when the sulfiting agent does bind with chemicals in the food. Bound sulfite includes reversibly bound and irreversibly bound sulfite. Under certain conditions, some of the bound sulfite molecules will dissociate, or break apart, and form free sulfite. The portion of bound sulfite that dissociates is called "reversibly bound sulfite." The bound sulfite that does not dissociate to form free sulfite is called "irreversibly bound sulfite." The distinction between reversibly and irreversibly bound sulfites is dependent on conditions in the food because some bound sulfite will dissociate under one set of conditions and not under others.

This discussion of terminology is necessary for a full understanding of several of the issues considered in this document.

Comments*Adequate Protection for Sensitive Individuals*

1. The comments from consumers supported the proposed labeling requirements. Most of the consumers who commented claimed to be sensitive to sulfites and wanted FDA to take strong measures to protect them from exposure to sulfites. Several specifically requested that FDA prohibit the use of sulfites in salad bar foods and other restaurant foods. Other comments stated that label declaration of sulfite alone would not provide adequate protection for sulfite-sensitive individuals. They, too, suggested stronger regulatory policies, including limiting certain uses of sulfites.

The agency agrees that labeling alone will not always provide adequate protection for sulfite-sensitive individuals. Based on its review of the most recent information available on the use of sulfites on fruits and vegetables intended to be served raw or sold raw to consumers or to be presented to consumers as fresh, FDA proposed to delete this use from the list of uses of sulfiting agents that are generally recognized as safe (GRAS) (August 14, 1985; 50 FR 32830). The only vegetables not covered by that proposal are potatoes. The adverse reactions suffered by sulfite-sensitive individuals after eating raw fruits and vegetables treated with sulfite are discussed in detail in the preamble to that proposal. Elsewhere in this issue of the *Federal Register*, FDA is issuing a final rule based on the August 14, 1985, proposal. The use of sulfites on fruits or vegetables intended to be

served raw to consumers, including the use of sulfiting agents in such salad bar or other restaurant foods, will not be permitted after the effective date of that final rule.

The agency is also still evaluating information on other uses of sulfites to decide whether any of them are no longer GRAS. The agency believes that once it has taken all actions on the use of sulfites that it considers necessary, sulfite-sensitive individuals will be adequately protected from unexpected exposure to sulfiting agents in foods.

2. One of the comments that urged stronger regulatory policies requested a mandatory warning statement on the principal display panel of the label.

FDA does not believe that it is necessary to require a warning statement on food labels. Sulfites are safe for most people, and the declaration of sulfiting agents in the list of ingredients will provide sufficient information for those people who need or want to avoid unexpected exposure to sulfites from packaged foods.

Foods Affected by the Proposal

3. Some comments requested clarification as to what foods would actually be covered by the proposal. Most of the confusion regarding the applicability of the proposal centered on foods in which sulfites have a technical or functional effect. Other comments, however, expressed confusion about the proposal's applicability to foods that contain sulfites that are indirectly added and that do not have a technical or functional effect. One comment wanted to know if the proposal applied to raw agricultural commodities as well as processed foods. Another wanted to know if label declaration of sulfiting agents would be required on shipments of food ingredients that would be further processed, mixed, or repackaged before sale to the final consumer. In addition, from the agency's ongoing enforcement activities regarding the use of sulfites in foods, it appears that confusion exists among food manufacturers and processors about how the requirements for labeling sulfiting agents apply to specific foods.

Section 403(k) of the act requires that if a food contains a chemical preservative, it must bear labeling stating that fact. As stated above, section 403(i)(2) of the act and FDA regulations (21 CFR 101.4) require that each ingredient in a food be declared on the label by its common or usual name but section 403(i)(2) also provides that where these declarations are impracticable, exemptions can be established. FDA has established such an exemption for ingredients described as

"incidental additives" in 21 CFR

101.100(a)(3) of its regulations.

Incidental additives may be processing aids (defined in §101.100(a)(3)(ii)), substances that are incorporated in a food as ingredients of another food, or substances that migrate to food from packaging. Regardless of how a substance gets into the food, if it has any technical or functional effect in the food, or if it is present in the food in a significant amount, it does not meet the definition of an incidental additive and is not entitled to the label exemption.

Thus, if a sulfiting agent has a technical or functional effect in the food, it must be declared in the ingredient listing regardless of the amount present. If the sulfiting agent functions as a chemical preservative, the labeling must state this fact in accordance with section 403(k) of the act.

The purpose of the current action is to make clear when sulfites are present in a food in a significant amount. Under §101.100(a)(4), when there is 10 ppm or more of a sulfite in the food, regardless of the source of the sulfite, it is present in a significant amount and must be declared in the ingredient list of the food.

FDA advises that 101.100(a)(4) would be applicable to raw agricultural commodities sold in bulk for consumption in the raw state as well as to processed foods. However, FDA has found that given the circumstances in which sulfites are used on raw agricultural commodities, those commodities cannot be effectively labeled. Consequently, as discussed above, elsewhere in this issue of the *Federal Register*, FDA is publishing a final rule containing the finding that the use of sulfites on fresh fruits and vegetables, except potatoes, is not GRAS. Because such a finding has the effect of prohibiting this use of sulfites, sulfites will cease to be used on most fruits and vegetables sold for consumption in the raw state. The GRAS status of sulfite use on potatoes will be addressed in a separate *Federal Register* document.

As for whether label declaration of sulfiting agents would be required on shipments of food ingredients that are to be further processed, mixed, or repackaged before retail sale, the agency advises that §101.100(d) of its regulations resolves this question. That section provides, among other things, that shipments of food to be processed, labeled, or repacked in substantial quantity need not bear ingredient declarations if there is a written agreement between the shipper and the receiver of the food that contains

information necessary for appropriate labeling of the food. Section 101.100(d) is not affected by this final rule. However, while the supplier of an ingredient must provide information for proper declaration of the ingredient in a finished food, the labeler of the finished food is legally responsible for the adequacy of the label (21 U.S.C. 331(a)). Therefore, the labeler has an obligation to ensure that it has the information necessary for appropriate label declarations.

To clarify current requirements for label declaration of sulfites, FDA has found it useful to describe three categories of food products that contain sulfites: (1) Those in which the sulfites are present below a detectable level (10 ppm) and for which there is general agreement that the sulfites present are nonfunctional; (2) those in which the sulfites are present at a detectable level (10 ppm or more) but do not have a technical or functional effect in the food; and (3) those in which the sulfites provide a technical or functional effect in the food. The labels of foods in the first category are not required to declare sulfites as ingredients. The labels of foods in the second category must declare the presence of sulfiting agents, but FDA will not take regulatory action for failure to declare the presence of those ingredients until after January 9, 1987. Foods in the third category have been and will continue to be subject to regulatory action if their labels fail to declare sulfiting agents, regardless of the level at which those substances are present.

Finally, the agency has revised the language of §101.100(a)(4) to make clear that the 10 ppm criterion for not declaring the presence of a sulfiting agent in a food applies only to sulfiting agents that have no technical or functional effect in the food being labeled. This revision is editorial only and does not change the substance of the paragraph in any way.

Basis for Sulfite Declaration

4. Many of the comments supported declaration of the presence of sulfiting agents when there are significant levels of sulfites in food. However, some comments asserted that the determination about the significance of the levels should be based on biological data rather than, as FDA has proposed, on analytical capability. These comments suggested that FDA consider: (1) That there is a general consensus among scientists that free sulfite is the sensitizing substance, and that bound sulfite does not trigger the kind of adverse reactions reported; (2) that

some of the new sulfite in food is bound and therefore not hazardous to sensitive individuals; (3) that 5 milligrams (mg) of sulfiting agent is the lowest dose documented to have caused an adverse reaction; and (4) that there is a threshold level of sulfite below which no adverse effect has been established.

FDA recognizes that there may be a consensus that free sulfite is the form of sulfite that poses the greatest risk to sensitive individuals. However, the Federation of American Societies for Experimental Biology's (FASEB) ad hoc Review Panel on Reexamination of the GRAS Status of Sulfiting Agents, acknowledged in its report that there was then no information available to show that bound sulfites may not also contribute to the adverse reactions. Since publication of this report, FDA has received preliminary information indicating that bound sulfites may also contribute to adverse reactions in humans. In the interest of consumer protection, therefore, and until more definitive scientific information becomes available, FDA believes that it must take into account the total amount of bound and unbound sulfite in a food.

The agency is also aware that the lowest ingested dose that has resulted in an adverse reaction to date is 5 mg of sulfiting agent. As reported by the Food Research Institute in its comment on the proposal, this instance involved a dose of 5 mg of potassium metabisulfite in a capsule, which is equivalent to about 3 mg sulfur dioxide. For an individual to obtain 3 mg of sulfur dioxide from a food with 10 ppm total sulfur dioxide, the person would have to consume 300 grams of food (about three-fourths of a pound).

The kinds of studies necessary to determine the level at which sulfite-sensitive people react to these substances have been performed on only a small number of individuals. Although FDA accepts the validity of the information provided in the comment, given the paucity of information, the agency does not consider that sufficient evidence is available to enable it to conclude that some sensitive individuals would not react adversely to smaller amounts of sulfite.

The agency also acknowledges that some studies indicate that sensitive individuals tend to tolerate higher levels of a sulfiting agent when it is administered on food than when administered by capsule or other clinical dosage form. However, too few individuals have been tested with sulfiting agents mixed with food to permit conclusions on how, why, or to

what extent ingestion with food may influence the reaction to sulfites.

In summary, the agency believes that the available information is inconclusive regarding whether there is a biological threshold level for sulfiting agents below which sensitive individuals will not experience adverse reactions. FDA believes, however, that it must act now to protect sensitive consumers. Accordingly, the agency is not using a biological criterion for determining what constitutes a significant level of sulfites. The criterion for labeling in this regulation is based on analytical capability as stated in the proposal.

5. One comment stated that there are extreme differences in the serving sizes of the foods affected by this regulation. The comment questioned the appropriateness of a single labeling criterion that did not take this variation into consideration.

Variation in serving size would be a significant factor if FDA were basing the labeling criterion on a biological threshold. However, as discussed in paragraph 4 of this preamble, FDA does not believe that it would be appropriate to use a biological threshold as the basis for label declaration of sulfites. The agency considers that the regulatory threshold of 10 ppm sulfite will adequately protect consumers of large servings as well as those who consume several servings of different foods containing sulfiting agents.

6. Some comments expressed concern that if sulfite labeling is based on the limit of detection for sulfite, then the trigger level will be lowered as the detection is lowered.

The agency is aware that much work is currently being done to lower the analytical detection limit for sulfites and to improve specificity. However, FDA wishes to reassure interested persons that it does not have plans to change the definition of a significant amount of sulfite based solely on improvements in methodology, unless justified by new data on the health consequences of sulfites in processed foods.

7. Some comments requested that FDA clarify the term "finished food" as the basis for determining the amount of sulfite present. The comments stated that the food "as served" was the appropriate form for determining sulfite content rather than "as sold." The comments cited juice concentrates, dry mixes, and refrigerated dough as examples of foods for which there was confusion in this regard.

The agency advises that ingredient declarations are based on the food as manufactured or packaged. Historically, FDA's ingredient declaration regulations

have required that those substances that have been used to manufacture a food are the ones that are to be included in the ingredient list for that food. The agency has not used the composition of the food at the time of consumption as the basis for ingredient declaration.

Consistent with the agency's historic policy, the nutrient quantities declared in nutrition labeling are based on the food as packaged (21 CFR 101.9(b)). Section 101.9(b) acknowledges that after retail sale some foods will undergo cooking or some other form of preparation during which nutrient quantities may change. Although that regulation permits a separate, additional declaration of the nutrient content of the food as consumed, the primary declaration of nutrient quantity is based on the food as packaged.

Section 101.100(a)(4) is consistent with this policy. These comments did not provide any reason for FDA to deviate from long-established policy in the case of declaration of sulfiting agents. The agency will continue to base any regulatory action on analysis of the food as manufactured or purchased.

Analytical Methodology

8. Many of the comments contended that the analytical methodology cited in the proposal was not suitable for enforcing the 10 ppm labeling criterion.

In selecting analytical methodology for the regulation of sulfites in food, FDA considered the complex nature of sulfite interaction with food. The methodology that FDA has chosen, the Monier-Williams procedure, is the official method of the Association of Official Analytical Chemists (AOAC), described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14 Ed. (1984), sections 20.123-20.125. FDA selected this method as the enforcement procedure because the analysis will measure the free sulfite plus a reproducible portion of the bound sulfites, such as the carbonyl addition products, in the food.

While it may be preferable to have a method that would measure, in absolute terms, the free sulfite and each of the other sulfite-derived substances in a food, FDA has determined that no such method exists, and that it is unlikely that one will be developed in the near future. Therefore, FDA has selected the Monier-Williams method, which for years has been the standard against which the accuracy of newer procedures has been judged, as the method that it will use for enforcement of the sulfite labeling rule.

The agency recognizes that the Monier-Williams method was not

originally intended to measure sulfite levels as low as 10 ppm. However, FDA has made some refinements in the method that, without changing its chemical principles, improve its accuracy and reproducibility and thus make it suitable for use at 10 ppm. The refinements that FDA has made include using a more dilute titrant and minor modifications in the apparatus. All of these changes, as well as other technical aspects of the analytical methodology, are discussed in detail in "A Report on the Monier-Williams Method for Sulfites in Food" (Monier-Williams Report), prepared by FDA. A copy of this report is on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. The modified procedure is described in "Monier-Williams Procedure (with Modifications) for Sulfites in Food" (November 1985) and is also on file in the Dockets Management Branch.

The Monier-Williams method consists of an isolation step and two determinative or quantitation steps. The sulfite is first isolated from the food as sulfur dioxide by distillation using vigorous refluxing in hydrochloric acid. The sulfur dioxide is then quantitated by a titrimetric procedure and sometimes also by a gravimetric procedure. Vigorous refluxing in hydrochloric acid ensures the release of all of the free sulfite and the recovery of a consistent portion of the reversibly bound sulfite (Monier-Williams Report, pp. 4-5). Accordingly, FDA will use the Monier-Williams isolation procedure in determining sulfite content of foods.

FDA has studied the precision of the Monier-Williams method (modified as discussed above) at 10 ppm and at 30 ppm, using three food matrices (fruit juice, shrimp, and hominy) (Monier-Williams Report, pp. 8-10). A statistical evaluation of the test results established that the modified Monier-Williams procedure is capable of determining sulfites in foods at levels of 10 ppm with an overall coefficient of variation ranging from 3.8 percent to 9.8 percent (average 7.0 percent). This range of coefficients of variation at 10 ppm is consistent with those established for other well-recognized regulatory analytical methods at the 10 ppm level.

9. Some comments stated that volatile organic acids and nitrous acid would cause direct interference with the titrimetric quantitative step in the Monier-Williams procedure.

The agency is aware of the potential for these interferences. The Monier-Williams procedure, however, includes a gravimetric quantitation procedure that can be used in addition to the

titrimetric procedure. The gravimetric step is free of interference from nitrites or volatile organic acids. When these kinds of interference are suspected in a food sample, e.g., in sugar or a syrup, FDA will use both the titrimetric and gravimetric procedures to assure that the analytical results are not inaccurate because of volatile acid interference.

10. Other comments pointed out that the Monier-Williams method is not capable of distinguishing between naturally occurring sulfite and sulfite added during processing. Some comments cited Brassica and Allium vegetables as examples of foods with naturally occurring sulfites.

Studies in FDA laboratories have demonstrated that onions and cabbage do, in fact, yield sulfur dioxide when subjected to refluxing hydrochloric acid as prescribed by the Monier-Williams method (Monier-Williams Report, pp. 10-11). Analysis of a limited number of fresh onion and cabbage samples has yielded sulfur dioxide responses ranging from 10 to 17 ppm. The agency has determined that the sulfur dioxide-yielding substances are sulfur-containing compounds that decompose in refluxing hydrochloric acid. Therefore, this problem is inherent not only in the Monier-Williams method but also in many other analytical procedures that depend on measurement of sulfur dioxide.

The agency intends to study the quantity of naturally occurring sulfur dioxide-yielding compounds in Allium and Brassica vegetables. Information from this study will be used to establish an upper limit for the natural sulfur dioxide response. FDA will take the existence of natural levels of sulfites into account in determining whether a shipment of food complies with the labeling requirement of this regulation.

The agency has no reason to believe that these naturally occurring sulfur dioxide-yielding compounds would cause adverse reactions in sulfite-sensitive individuals. These foods have been consumed safely. There is no record of sulfite-type adverse reactions to Allium and Brassica vegetables that do not contain added sulfiting agent.

11. Other comments stated that the Monier-Williams procedure gives false-positives.

FDA is aware of this problem in a few instances but believes that it may result from a lack of sample homogeneity or may be a direct consequence of the instability of sulfite. This problem, therefore, is likely to be inherent in any method used to analyze for sulfite. With the Monier-Williams method, careful attention must be given to certain aspects of the analysis. For example, the

reflux condenser must be chilled with a very cold coolant. The significant procedures in the analysis are outlined in the Monier-Williams Report. FDA believes that if these significant procedures are properly followed, the Monier-Williams method is reliable.

12. Several comments pointed out that, for a food with about 10 ppm sulfite, the sample size specified in the official AOAC version of the Monier-Williams procedure would be too large to be practical.

FDA advises that reducing a sample size is one of the refinements that the agency has made to make the Monier-Williams procedure appropriate for use at 10 ppm. This change and the others that FDA has made are described in the Monier-Williams Report.

13. A few comments stated that the Monier-Williams procedure was not suitable for quality control use in monitoring sulfite content of foods.

The agency advises that processors are under no obligation to use the designated analytical procedure for quality control or for any other purpose. The agency will, however, use the Monier-Williams procedure as the basis for its enforcement activities. Processors frequently compare the analytical method of their choice to FDA's designated enforcement method and use their method of choice as they see fit.

Other Comments

14. A number of comments requested that FDA provide flexibility in the declaration of sulfiting agents, i.e., relief from the requirement that each sulfiting agent in a food be declared by its common or usual name. The comments argued that flexibility was desirable because (1) the proposed regulation would require declaration of sulfiting agents present as components of ingredients of the finished food; (2) the sulfiting agent in an ingredient might vary among different suppliers of the ingredient; and (3) there may be more than one sulfite-bearing ingredient, and it would be impossible to determine which sulfiting agents contributed to the detectable sulfite in the finished food. Several comments suggested that a collective term like "sulfiting agents" or "sulfur dioxide" would provide labeling flexibility while providing all necessary information to the consumer. One comment suggested using a collective term with "and/or" labeling. Another comment suggested that when a sulfiting agent is added directly to a food that also contains indirectly added sulfite, declaration of the directly added agent by its name should be sufficient. The comment said that it should not be

necessary also to declare the indirectly added sulfiting agents.

With regard to sulfiting agents that are directly added to, or that have a technical effect in, food, the name of the specific sulfiting agent that is added must be declared on the label. However, the agency agrees with the comments that some flexibility is warranted in the declaration of sulfiting agents that are indirectly added to a food and that have no technical or functional effect in the food. An indirectly added sulfite is present in a food as a component of an ingredient in the food, as a processing aid, or as a migrant from food packaging. The purpose of declaring sulfiting agents that are indirectly added and that have no technical or functional effect is to provide information to the consumer who wishes to avoid foods that contain sulfites. FDA believes that there is no reason to expect that one sulfiting agent acts differently from the others in causing adverse reactions. Accordingly, FDA believes that when sulfite is indirectly added to a food and does not have a technical or functional effect in the food, the identity of the specific sulfiting agent is not significant to the sensitive consumer.

In light of this conclusion, the agency considers that a collective term that applies to all six sulfiting agents would provide appropriate labeling flexibility without depriving the consumer of any significant information. Of the collective terms suggested by the comments, FDA considers "sulfiting agents" to be the most accurate and informative. "Sulfur dioxide" is one of the sulfiting agents and use of this term when one or more of the other agents have been used could be misleading. As discussed above, "sulfites" is a relatively informal term whose meaning is not always clear to the reader.

As suggested in a comment, FDA will consider amending the regulation in which collective terms permitted in ingredient declarations are listed (21 CFR 101.4(b)). However, pending promulgation of a provision in § 101.4(b), the agency will not take legal action against foods that declare sulfiting agents as follows: (1) When sulfiting agents that remain in a food in a significant amount but no longer have a technical or functional effect, they may be declared by the term "sulfiting agents;" and (2) when a food contains a sulfiting agent that has a technical or functional effect in the food and that is declared in the list of ingredients by its common or usual name, any nonfunctional sulfiting agents present in the food need not be declared separately in the list of ingredients.

However, FDA emphasizes that this flexibility applies only if the sulfite does not perform a technical or functional effect in the food.

15. One comment reflected confusion about the declaration required by this regulation. The comment objected to declaration of the amount of sulfite present in a food.

The agency advises that there is no requirement for quantitative declaration of sulfites. The only information that is required to be included in the label is the name of the sulfiting agent, or, in the circumstances explained above in paragraph 14, the term "sulfiting agents."

16. Some comments requested that there be more than 6 months between publication of the final regulation and its effective date. Some requested a minimum of 12 months, others 18 months. Several comments also requested that FDA use the next uniform effective date because (1) the hazard to sulfite-sensitive individuals from packaged foods is not well-documented; (2) this regulation is a labeling regulation and should have the effectiveness interval usually used for labeling regulations; (3) some sulfited products are packed seasonally, and provision must be made for the timing of the seasons; (4) foreign produce that is contra-seasonal would have an unfair advantage over domestic produce; and (5) more time is necessary for depletion of label inventories.

This labeling regulation has as its basis a serious health concern. Although FDA is sympathetic to the problems processors will encounter with a 6-month interval, it cannot ignore the potential hazard to sulfite-sensitive consumers. Of the approximately 500 complaints from individual consumers who reported adverse responses, 14 percent specifically mentioned having had a reaction after eating processed, packaged food at home. Additionally, in recent months the agency has analyzed a number of foods that contained significant amounts of sulfite but that were not so labeled. This finding emphasizes the need for clarification of the labeling requirements for sulfiting agents as quickly as is feasible to facilitate compliance. The requirement to declare the presence of sulfiting agents on the label when they are added for a technical or functional effect is not changed by this labeling regulation, and therefore the effective date does not apply to these foods. The effective date provision applies to foods affected by this regulation that are initially introduced into interstate commerce. FDA will not take regulatory action

against foods subject to this regulation that are already in interstate distribution on the effective date.

17. A trade association for the wine industry commented on this proposal even though labeling of wines is regulated by the Bureau of Alcohol, Tobacco and Firearms (BATF) of the Department of the Treasury. In the *Federal Register* of June 24, 1985 (50 FR 26001), BATF published a proposal that would require declaration of sulfiting agents in beverage alcohol products if the sulfites exceed the amount in FDA's definition of detectable amount (10 ppm). The association acknowledged that wines are under BATF's jurisdiction but commented on FDA's proposal because of BATF's declared reliance on FDA's regulation.

The issues raised in the comment relate directly to wine and have no bearing on the action that FDA is taking. Therefore, FDA is not responding to this comment. The agency considers that it is not appropriate for it to revise its labeling policy for a product that is not subject to that policy and for which it has neither information nor expertise. FDA has, however, forwarded the comment to BATF for its consideration.

18. One comment requested that FDA adopt a policy of Federal preemption for labeling of sulfiting agents. The comment cited several court decisions in support of its argument that preemption was feasible.

The agency does not use its authority to preempt State requirements unless there is a genuine need to stop the proliferation of inconsistent requirements between FDA and the States. FDA is not persuaded that such a need now exists with regard to sulfite labeling. The agency will, however, evaluate any information concerning a need for Federal preemption that is submitted to it and will take appropriate action.

Environmental Impact

The agency has determined under 21 CFR 25.24(b)(7) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Economic Impact

This regulation clarifies an existing regulatory requirement. Therefore, the regulation will have no economic effect. However, because FDA recognizes that there has not been universal compliance with this requirement, the agency

examined, in accordance with Executive Order 12291, the potential economic consequences of requiring that sulfiting agents be declared on the label when present in food in a detectable amount as though this requirement were new. On the basis of available information, the agency determined that this regulation may impose one-time costs of \$1.3 million. The agency has not received any new information or comments that would alter its previous determination and, therefore, the agency has determined that the rule is not a major rule as defined by the Order.

Furthermore, FDA, in accordance with the Regulatory Flexibility Act, had considered the effect that this final rule will have on small entities, including small businesses, and has concluded that the regulation will require a label change resulting only in a minimal impact on any individual firm. Approximately 450 small firms may incur costs totaling about \$300,000. It is unlikely that any small firms will bear excessive or unreasonable burdens as a result of this regulation. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will be caused by this regulation. The agency has not received any new information or comments that would alter its previous determination.

Two comments disagreed with FDA's estimate of the economic impact on this regulation. One comment stated that cost increases would probably exceed \$100 million. The comments averred that this impact would result from food manufacturers discontinuing the use of sulfites in their foods to avoid declaring them. Not using sulfites would, one comments stated, result in expensive equipment changes and even in the failure of certain industries.

The agency does not agree that this kind of impact is likely. The comments' arguments are based on the assumption that certain nonsensitive consumers would overreact and avoid foods that declare sulfites in the list of ingredients. Although it is likely that sulfite-sensitive individuals will avoid sulfite-labeled foods, the agency does not believe that such product avoidance will occur among individuals who are not sulfite sensitive. A large number of foods that are currently on the market bear a sulfite declaration, and the agency has not seen any indication that there has been a significant reduction in the marketability of these foods.

In addition, many of the foods that contain a significant amount of sulfites under § 101.100(a)(4) are multi-ingredient foods whose label already

declares the presence of several ingredients. The agency has no reason to believe that the addition of one more term to the list of ingredients would significantly affect marketability. Consequently, FDA is not revising its estimate of the economic impact of this action.

List of Subjects in 21 CFR Part 101

Food labeling; Incorporation by reference; Misbranding; nutrition labeling; Warning statements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR Part 101 is revised as set forth below and the authority citations under 21 CFR 101.2, 101.3, 101.4, 101.9, 101.10, 101.11, 101.13, 101.17, 101.22, 101.33, 101.105, and 101.108 are removed.

Authority: Secs. 4, 6, Pub. L. 89-755, 80 Stat. 1297, 1299, 1300 (15 U.S.C. 1453, 1455); secs. 403, 701, Pub. L. 717, 52 Stat. 1047-1048 as amended, 1055-1056 as amended (21 U.S.C. 343, 371); 21 CFR 5.10 and 5.11; § 101.11 is issued only under secs. 201(s), 403(p), 409, 701(a), Pub. L. 717, 52 Stat. 1055, 72 Stat. 1784-1788 as amended, 91 Stat. 1453 (21 U.S.C. 321(s), 343(p), 348, 371(a)) and Pub. L. 95-203, 91 Stat. 1451-1454 (21 U.S.C. 301 note); § 101-100(a)(4) is issued only under secs. 403 and 701, 52 Stat. 1047-1048 as amended, 1055-1056 as amended (21 U.S.C. 343, 371).

2. Section 101.100 is amended by adding new paragraph (a)(4), to read as follows:

§ 101.100 Food; exemptions from labeling.

(a) * * *

(4) For the purposes of paragraph (a)(3) of this section, any sulfiting agent (sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite) that has been added to any food or to any ingredient in any food and that has no technical effect in that food will be considered to be present in an insignificant amount only if no detectable amount of the agent is present in the finished food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. Compliance with this paragraph will be determined using sections 20.123-20.125, "Total Sulfurous Acid," in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th Ed. (1984), which is incorporated by reference and the refinements of the "Total Sulfurous Acid" procedure in the "Monier-Williams Procedure (with Modifications) for Sulfites in Foods," which is Appendix A to Part 101. A copy of

sections 20.123-20.125 of the Official Methods of Analysis of the Association of Official Analytical Chemists" is available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

3. Appendix A is added to Part 101 to read as follows:

Appendix A for Part 101—Monier-Williams Procedure (With Modifications) for Sulfites in Food, Center for Food Safety and Applied Nutrition, Food and Drug Administration (November 1985)

The AOAC official method for sulfites (*Official Methods of Analysis*, 14th Edition, 20.123-20.125, Association of Official Analytical Chemists) has been modified, in FDA laboratories, to facilitate the determination of sulfites at or near 10 ppm in food. Method instructions, including modifications, are described below.

Apparatus—The apparatus shown diagrammatically (Figure 1) is designed to accomplish the selective transfer of sulfur dioxide from the sample in boiling aqueous hydrochloric acid to a solution of 3% hydrogen peroxide. This apparatus is easier to assemble than the official apparatus and the back pressure inside the apparatus is limited to the unavoidable pressure due to the height of the 3% H_2O_2 solution above the tip of the bubbler (F). Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks.

The apparatus should be assembled as shown in Fig. 1 with a thin film of stopcock grease on the sealing surfaces of all the joints except the joint between the separatory funnel and the flask. Each joint should be clamped together to ensure a complete seal throughout the analysis. The separatory funnel, B, should have a capacity of 100 ml or greater. An inlet adapter, A, with a hose connector (Kontes K-183000 or equivalent) is required to provide a means of applying a head of pressure above the solution. (A pressure equalizing dropping funnel is not recommended because condensate, perhaps with sulfur dioxide, is deposited in the funnel and the side arm.) The round bottom flask, C, is a 1000 ml flask with three 24/40 tapered joints. The gas inlet tube, D, (Kontes K-179000 or equivalent) should be of sufficient length to permit introduction of the nitrogen within 2.5 cm of the bottom of the flask. The Allihn condenser, E, (Kontes K-431000-2430 or equivalent) has a jacket length of 300 mm. The bubbler, F, was fabricated from glass according to the dimensions given in Fig. 2. The 3% hydrogen peroxide solution can be contained in a vessel, G, with an i.d. of ca. 2.5 cm and a depth of 18 cm.

Buret—A 10 ml buret (Fisher Cat. No. 03-848-2A or equivalent) with overflow tube and hose connections for an Ascarite tube or equivalent air scrubbing apparatus. This will permit the maintenance of a carbon dioxide-

free atmosphere over the standardized 0.01N sodium hydroxide.

Chilled Water Circulator.—The condenser must be chilled with a coolant, such as 20% methanol-water, maintained at 5 °C. A circulating pump equivalent to the Neslab Coolflow 33 is suitable.

Reagents

(a) **Aqueous hydrochloric acid, 4N.**—For each analysis prepare 90 ml of hydrochloric acid by adding 30 ml of concentrated hydrochloric acid (12N) to 60 ml of distilled water.

(b) **Methyl red indicator.**—Dissolve 250 mg of methyl red in 100 ml ethanol.

(c) **Hydrogen peroxide solution, 3%.**—Dilute ACS reagent grade 30% hydrogen peroxide to 3% with distilled water. Just prior to use, add three drops of methyl red indicator and titrate to a yellow end-point using 0.01N sodium hydroxide. If the end-point is exceeded discard the solution and prepare another 3% H₂O₂ solution.

(d) **Standardized titrant, 0.01N NaOH.**—Certified reagent may be used (Fisher SO-5-284). It should be standardized with reference standard potassium hydrogen phthalate.

(e) **Nitrogen.**—A source of high purity nitrogen is required with a flow regulator that will maintain a flow of 200 cc per minute. To guard against the presence of oxygen in the nitrogen, an oxygen scrubbing solution such as an alkaline pyrogallol trap may be used. Prepare pyrogallol trap as follows:

1. Add 4.5 g pyrogallol to the trap.
2. Purge trap with nitrogen for 2 to 3 minutes.
3. Prepare a KOH solution prepared by adding 65g KOH to 85 ml distilled water (caution: heat).

4. Add the KOH solution to the trap while maintaining an atmosphere of nitrogen in the trap.

Determination

Assemble the apparatus as shown in Fig. 1. The flask C must be positioned in a heating mantle that is controlled by a power regulating device such as Variac or equivalent. Add 400 ml of distilled water to flask C. Close the stopcock of separatory funnel, B, and add 90 ml of 4N hydrochloric acid to the separatory funnel. Begin the flow of nitrogen at a rate of 200±10 cc/min. The condenser coolant flow must be initiated at this time. Add 30 ml of 3% hydrogen peroxide, which has been titrated to a yellow end-point with 0.01N NaOH, to container G. After fifteen minutes the apparatus and the distilled water will be thoroughly de-oxygenated and the apparatus is ready for sample introduction.

Sample preparation (solids).—Transfer 50 g of food, or a quantity of food with a convenient quantity of SO₂ (500 to 1500 mcg SO₂), to a food processor or blender. Add 100 ml of 5% ethanol in water and briefly grind the mixture. Grinding or blending should be continued only until the food is chopped into pieces small enough to pass through the 24/40 point of flask C.

Sample preparation (liquids).—Mix 50 g of the sample, or a quantity with a convenient quantity of SO₂ (500 to 1500 mcg SO₂), with 100 ml of 5% ethanol in water.

Sample introduction and distillation.—Remove the separatory funnel B, and quantitatively transfer the food sample in aqueous ethanol to flask C. Wipe the tapered joint clean with a laboratory tissue, apply stopcock grease to the outer joint of the separatory funnel, and return the separatory

funnel, B, to tapered joint flask C. The nitrogen flow through the 3% hydrogen peroxide solution should resume as soon as the funnel, B, is re-inserted into the appropriate joint in flask C. Examine each joint to ensure that it is sealed.

Apply a head pressure above the hydrochloric acid solution in B with a rubber bulb equipped with a valve. Open the stopcock in B and permit the hydrochloric acid solution to flow into flask C. Continue to maintain sufficient pressure above the acid solution to force the solution into the flask C. The stopcock may be closed, if necessary, to pump up the pressure above the acid and then opened again. Close the stopcock before the last few milliliters drain out of the separatory funnel, B, to guard against the escape of sulfur dioxide into the separatory funnel.

Apply the power to the heating mantle. Use a power setting which will cause 80 to 90 drops per minute of condensate to return to the flask from condenser, E. After 1.75 hours of boiling the contents of the 1000 ml flask and remove trap G.

Titration.—Titrate the contents with 0.01N sodium hydroxide. Titrate with 0.01N NaOH to a yellow end-point that persists for at least twenty seconds. Compute the sulfite content, expressed as micrograms sulfur dioxide per gram of food (ppm) as follows:

$$\text{ppm} = (32.03 \times V_B \times N \times 1000) \div W_t$$

where 32.03 = milliequivalent weight of sulfur dioxide; V_B = volume of sodium hydroxide titrant of normality, N, required to reach endpoint; the factor, 1000, converts milliequivalents to microequivalents and W_t = weight (g) of food sample introduced into the 1000 ml flask.

Figure 1. The optimized Monier-Williams apparatus. Component identification is given in text.

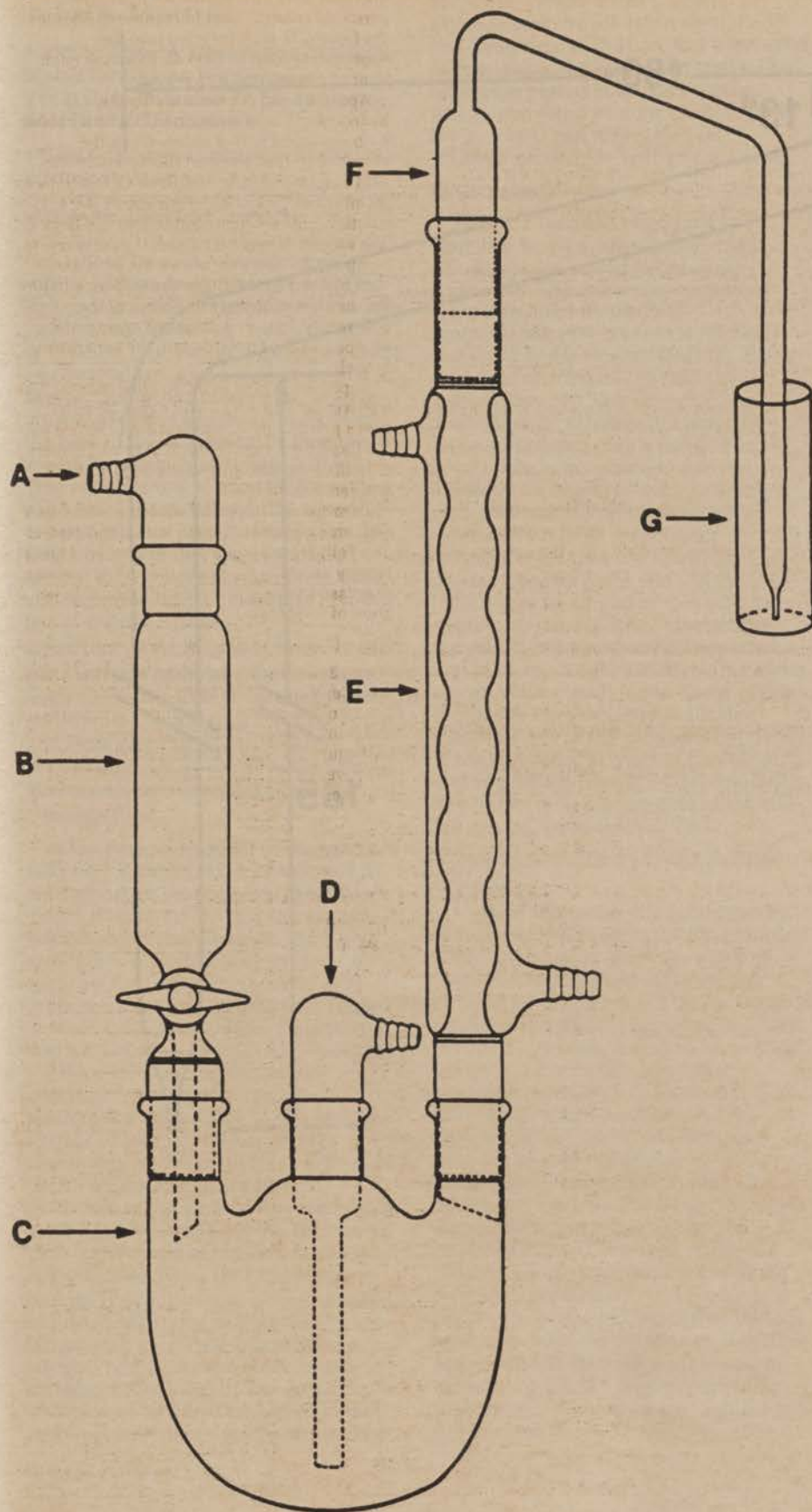
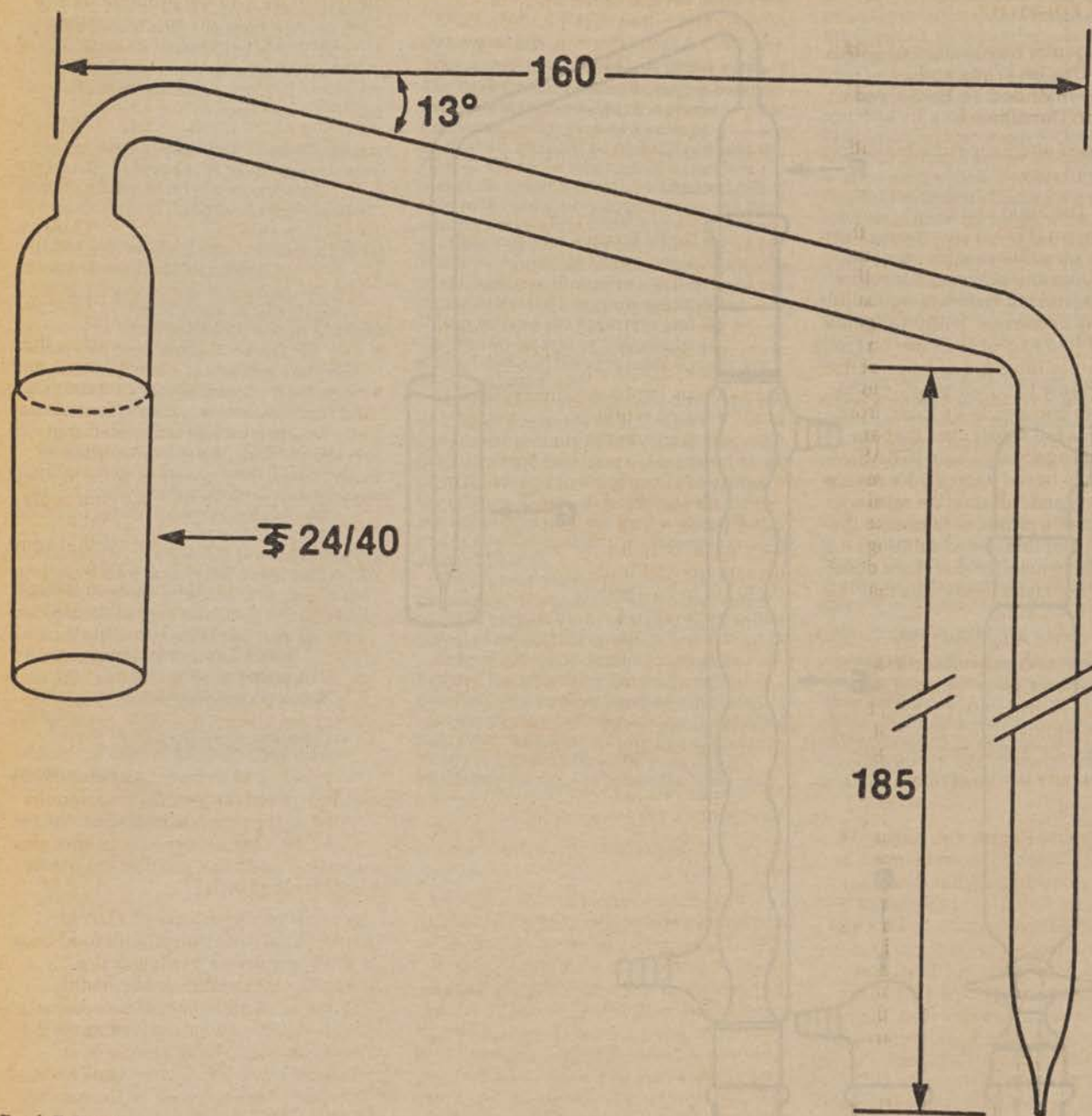


Figure 2. Diagram of bubbler (F in Figure 1). Lengths are given in mm.



Frank E. Young,
Commissioner of Food and Drugs.
Otis R. Bowen,
Secretary of Health and Human Services.

Dated: June 11, 1986.

[FR Doc. 86-15390 Filed 7-8-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 182

[Docket No. 81N-0314]

Sulfiting Agents; Revocation of GRAS Status for Use on Fruits and Vegetables Intended To Be Served or Sold Raw to Consumers**AGENCY:** Food and Drug Administration.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations on sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite (collectively known as "sulfiting agents" or "sulfites") to except their use on fruits and vegetables intended to be served raw or sold raw to consumers, or to be presented to consumers as fresh, from the uses of these substances that are generally recognized as safe (GRAS). This action is based upon FDA's review of comments and information received in response to a proposal to revoke the GRAS status of this use of sulfiting agents. FDA concludes that there does not currently exist a consensus that this use of sulfites is safe.

EFFECTIVE DATE: August 8, 1987.**FOR FURTHER INFORMATION CONTACT:**

Mary C. Custer, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. 202-426-9463.

SUPPLEMENTARY INFORMATION:**I. Background.**

In the Federal Register of August 14, 1985 (50 FR 32830), FDA announced its preliminary conclusion that there is no longer a basis to find that the use of sulfites as preservatives on fruits and vegetables intended to be served raw or sold raw to consumers is GRAS and proposed to amend 21 CFR Part 182 to exclude this use of sulfites from those that are listed as GRAS under Part 182.

FDA published its preliminary conclusion after reviewing new information on sulfiting agents from a variety of sources, including: (1) Comments on the proposal to affirm the GRAS status of sulfiting agents published in the Federal Register of July 9, 1982 (47 FR 29956); (2) the January 31, 1985, final report of the Federation of American Societies for Experimental Biology (FASEB) on the Reexamination of the GRAS Status of Sulfiting Agents; (3) recently published reports in the medical literature; and (4) consumer complaints received by the agency.

Copies of all data referenced in the proposal and other documents used in

developing the proposal were available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. FDA allowed a period of 30 days during which interested persons could review the proposal and other relevant information and file written comments.

II. Comments

FDA received 553 comments in response to the proposal. Individual consumers submitted 497 of these comments. The remaining comments were submitted by medical professionals (17); scientists (3); State and local health departments (8); State government officials (2); medical associations (4); food manufacturers, processors, or retailers (9); industry trade associations (9); a public health association; a government agency; a member of Congress; and a consumer group. Almost all of the comments agreed with FDA's preliminary conclusion that the use of sulfites as a preservative on fruits and vegetables intended to be served raw or sold to consumers is not GRAS. Most of the comments from consumers requested that FDA revoke the GRAS status of the use of sulfites in all foods. Some of the comments from industry requested modifications of the proposed regulation to exempt specific types of fresh fruits and vegetables from the final regulation. The issues raised in the comments and the agency's responses follow.

A. Adequate Protection for Sensitive Individuals

1. All of the comments submitted by consumers (497) supported the proposed GRAS revocation. More than half of these consumers (306) reported that either they or a close relative or friend is sensitive to sulfite-treated foods. Many described adverse reactions of varying severity to foods that they knew contained sulfites or to foods that they believed contained sulfites. A few consumers requested that FDA also prohibit the use of sulfiting agents on certain specific foods, including all restaurant food, seafood, beer, potatoes, frozen food, and wine. The majority of consumers (315), however, requested that the agency prohibit the use of the sulfiting agents on all food products. Some consumers (46) requested that the agency at least curtail the use of sulfites or require full disclosure of the use of sulfiting agents if a ban on particular food uses or all food uses of sulfites is not feasible.

All but 1 of the 21 comments submitted by medical professionals or medical associations supported the proposed GRAS revocation. One medical professional opposed the proposed action on the basis that sulfites contribute to the overall cleanliness of salad bars. Six medical professionals reported that either they or a close relative or patients under their care were sensitive to sulfites. A majority of medical professionals (11) requested that FDA prohibit the use of the sulfiting agents on all food products.

All 13 comments submitted by State health departments, local health departments, government agencies, the member of Congress, State officials, and public health associations supported the proposed GRAS revocation. Two of the State health departments stated that laws prohibiting the use of sulfites on fresh fruits and vegetables were in effect in their States. Four of these comments referred to surveys showing that a majority of the establishments that were using sulfites were not notifying consumers of this practice, even though in some instances, such notification was required by State law. Three States and a public health association requested that FDA either prohibit or limit the use of sulfites on potatoes, while two State officials requested that FDA prohibit the use of sulfites in all foods.

Nine of the 18 comments submitted by industry or industry trade associations supported the proposed GRAS revocation. One of these comments also requested that FDA prohibit the use of sulfites in all foods.

A consumer group asked FDA to revoke the GRAS status of all food uses of sulfites unless a particular use performs an essential public health function for which there is no adequate substitute. The comment further stated that ingredient labeling alone is inadequate given the severity of some of the reported responses and the number of individuals that may be at risk.

Based upon its tentative conclusion that a consensus no longer exists that the use of sulfites on fresh fruits and vegetables is safe, FDA proposed to remove this use from the list of uses of these substances that are GRAS. The vast majority of comments from experts qualified by scientific training and experience to evaluate the safety of this use agreed that the use of sulfites on fresh fruits and vegetables is not safe. Therefore, the agency finds that its tentative conclusion is correct, and that

the use of sulfites on fresh fruits and vegetables is not GRAS.

The agency is currently evaluating other information on sulfites in order to decide whether any other uses of these ingredients should be excluded from GRAS status. The agency intends to address the GRAS status of all other uses of sulfiting agents, including their use on potatoes and potato products, in the near future. In addition, elsewhere in this issue of the *Federal Register*, FDA is publishing a final rule that requires that all packaged foods that contain 10 parts per million (ppm) or more of sulfur dioxide equivalents be labeled to disclose the presence of the sulfiting agent (50 FR 13306; April 3, 1985).

2. A few consumer comments requested mandatory warning statements regarding sulfites in restaurants or on packaged, processed foods.

The agency believes that the action it is taking in this final rule will afford more effective protection for sulfite-sensitive individuals than mandatory warning statements in restaurants. This conclusion is based upon the results of FDA's efforts to encourage retail food establishments to disclose the use of sulfites via placards or notes on menus. The lack of effectiveness of this FDA labeling recommendation is reflected in several of the comments submitted by health departments and reviewed in paragraphs 1 and 10 of this preamble. As shown by the surveys discussed in these comments, comprehensive enforcement of the agency's labeling recommendation has proven difficult. Therefore, FDA concludes that at least in the case of sulfite-treated fresh fruits and vegetables, labeling requirements, including warning statements, will not afford adequate protection to sulfite-sensitive individuals.

The issue of sulfite declaration on packaged, processed foods is addressed in the final rule that is published elsewhere in this issue of the *Federal Register*. For the reasons discussed in that document, FDA finds that it is not necessary to require warning statements regarding sulfites on packaged foods that contain these ingredients.

B. Foods Affected by the Proposal

3. Some comments requested clarification as to which foods would be covered by the proposal. Some of the confusion regarding the applicability of the proposal centered on foods that are blanched and require further cooking before consumption, such as some frozen vegetables. One comment suggested that the agency insert the word "unblanched" in parenthesis after the word "raw" in the regulation and

add the statement "and which are intended to be consumed without further cooking" at the end of the regulation.

The regulation is not intended to apply to blanched products that are to be further cooked before consumption, but it will apply to raw, frozen foods that are simply thawed before consumption, such as frozen guacamole and some frozen fruits. The agency believes that the coverage of the regulation is already clear, and that additional language in the regulation is not needed.

4. One comment inquired whether the proposal covered raw produce that is sold to consumers in labeled packaging. A second comment requested that FDA specifically exclude this type of produce from the proposed GRAS revocation.

The regulation covers packaged raw produce. As explained in the proposal, consumers do not generally expect raw fruits and vegetables that have the appearance of freshness to contain preservatives. In addition, because the majority of raw fruits and vegetables sold in grocery stores are sold in bulk and are not usually labeled, consumers are not likely to associate raw produce with the presence of preservatives such as sulfiting agents. Therefore, FDA believes that it would not be in the public interest to exclude raw, packaged produce from the coverage of this action, and the agency has not adopted this suggestion in the final regulation.

5. One processor requested that FDA permit distribution of frozen guacamole (avocado) until stock produced before August 14, 1985, is exhausted. The processor estimated that its product would probably not be fully distributed until September 1986.

This regulation has as its basis a serious health concern. Although FDA is aware that a few processors may encounter problems with the effective date of this regulation, the agency believes that in this instance, addressing the potential hazards to sulfite-sensitive individuals must take precedence over processors' problems arising from distribution and depletion of existing stocks. Therefore, FDA is not granting any exemption for existing stock from the effective date of the final rule.

C. Alternative Regulatory Actions

6. Several comments expressed the opinion that the agency appeared to be relying on anecdotal evidence and requested that action on the proposed GRAS revocation await the results of further scientific research. Some comments suggested that FDA should encourage and initiate research designed to develop alternatives to sulfites, to characterize the specific

chemical reactions that occur between sulfites and other food components, and to determine the role of free and bound sulfites in triggering allergic-type responses in susceptible individuals. The comments also urged FDA to encourage clinical research designed to ascertain safe threshold doses of sulfite-treated foods for sulfite-sensitive individuals.

FDA recognizes the value of the suggested research initiatives and does encourage efforts to develop useful information about the safety of the use of sulfites in food. Furthermore, in the proposal, FDA specifically requested evidence as to whether an association exists between exposure to sulfites on fresh fruits and vegetables and adverse responses in sulfite-sensitive individuals. However, no substantive data regarding the safe use of sulfites on raw, fresh fruits and vegetables were submitted in response to this request.

The agency did receive, and subsequently deny, a request to extend the comment period through December 31, 1985, with respect to raw mushrooms. This request stated that studies on the risks from sulfite-treated raw mushrooms to sulfite-sensitive individuals would be initiated in about mid-October 1985.

As noted above, the purpose of this regulation is to respond to a serious health concern. Although the agency encourages the type of research mentioned in the extension request, such research could take years to complete. Potential hazards to sulfite-sensitive individuals will continue while such research is being conducted. For this reason, the agency is not postponing action on the GRAS status of the use of sulfites on fresh fruits and vegetables pending completion of further scientific research. However, once this research has been completed, the results can be submitted for agency review to determine whether the use of sulfites on fresh mushrooms has been shown to be safe through scientific procedures, and whether this use can be restored to GRAS status.

7. A few comments opposed the proposed regulation and suggested that the agency adopt alternative regulatory action. One comment requested that the agency set good manufacturing practice maximum residue levels for individual raw commodities at the point of consumption. This comment also requested that FDA establish safe levels of free or bound sulfites for each commodity. A second comment stated that all uses of sulfites on raw produce have not been confirmed as hazardous, and that some raw produce with low

sulfite residues will not be hazardous. The comment requested that FDA allow sulfite use on raw produce with nonhazardous residues.

FDA finds that it is not possible to adopt any of the alternate regulatory approaches suggested in the comments. The agency believes that the available information is inconclusive as to whether there is a threshold level of sulfiting agents below which sensitive individuals will not experience adverse reactions and as to how high that level might be. The agency is aware that, in the testing of sulfites that has been done, the lowest ingested dose that has resulted in an adverse reaction is 5 milligrams of potassium metabisulfite in a capsule, which is equivalent to about 3 milligrams of sulfur dioxide. Although FDA accepts the validity of this information, the kinds of studies necessary to determine the level at which sulfite-sensitive people react to sulfites have been performed on a relatively small number of individuals. The agency does not consider that sufficient evidence is available to conclude that some sensitive individuals would not react adversely to smaller amounts of sulfite.

The agency also acknowledges that some studies indicate that sensitive individuals tolerate higher levels of a sulfiting agent when it is administered in food than when administered by capsule or other clinical dosage form. However, too few individuals have been tested with sulfite-treated food to permit conclusions as to how or why or to what extent ingestion with food matrix influence the reaction to sulfites. Therefore, FDA finds that, given currently available information, it is not possible to set good manufacturing practice or other types of nonhazardous residue levels for sulfites.

FDA recognizes that there may be a consensus that free sulfite is the form of sulfite that poses the greatest risk to sensitive individuals. However, the Federation of American Societies for Experimental Biology's (FASEB) ad hoc Review Panel on Reexamination of the GRAS status of Sulfiting Agents, acknowledged in its report that there was then no information available to show that bound sulfites may not also contribute to the adverse reactions. Since publication of this report, FDA has received preliminary information indicating that bound sulfites may also contribute to adverse reactions in humans. In the interest of consumer protection, therefore, and until more definitive scientific information becomes available, FDA believes that it

must take into account the total amount of bound and unbound sulfite in a food.

FDA believes that resolution of the issues that bear on a safe level of sulfite use will not be forthcoming in the near future. The resolution of these issues is dependent upon clinical research involving human subjects and considerable time and effort. It is FDA's obligation, however, to act now to protect sensitive individuals. Accordingly, the agency is adopting a regulatory course of action regarding raw produce that does not depend upon the establishment of safe tolerance levels for specific raw commodities. As stated in the response to the previous comment (6), if data regarding the establishment of a safe tolerance level of sulfite for a raw commodity become available, they may be submitted for agency review as part of a GRAS or food additive petition.

D. Other Issues

8. One comment requested that the agency clearly define the term "consumer," and that the agency specifically state whether this term includes intermediate food processors.

The agency advises that in the current regulation, "consumer" refers to the individual who purchases food for consumption, and that this term does not include intermediate food processors.

9. One issue about which FDA specifically requested information was whether there are alternatives to the use of sulfites on fresh fruits and vegetables.

Although some comments contained references to alternatives to the use of sulfites, no new information on this issue was submitted in response to the proposal. Two comments contended that no practical alternative to the use of sulfites on fresh mushrooms exists. However, these comments did not submit any new information or controlled studies in support of their contention. On the other hand, another comment from a mushroom grower supported the proposed GRAS revocation and stated that it had successfully discontinued its use of sulfites. Another industry comment submitted information on the use of citric acid, erythorbic acid, and ascorbic acid as alternatives for sulfites on fresh vegetables. However, this information had been evaluated by the agency before it drafted the proposed regulation. Nevertheless, the existence of these alternatives shows that FDA's action will not have a major negative impact on the food industry.

10. Another issue about which FDA specifically requested information was the extent to which food-service

establishments, grocery stores, and produce handlers currently use sulfiting agents on fresh fruits and vegetables.

Several comments discussed various aspects of this issue. Three comments included information derived from official or unofficial surveys on the use of sulfites in food-service establishments and grocery stores. One official State survey found that approximately 15 percent of the surveyed establishments used sulfiting agents. Another unofficial State survey found that a substantial number of restaurants were using sulfiting agents without providing public notice of this practice.

A third State survey, taken in 1983 and repeated in 1985, revealed that in 1983, 9 percent of the surveyed retail establishments used sulfiting agents. The survey found that by 1985, this figure had dropped to 1 percent, but that 9 percent of the surveyed establishments were purchasing products that had been sulfited at the wholesale level. A fourth survey revealed that 10 percent of the more than 2,000 surveyed establishments used sulfiting agents, and that 90 percent of these users were not notifying patrons of this use. One comment discussed the extent of use of sulfites on fresh mushrooms in one county in Pennsylvania, and another comment included a December 1984 survey of fresh produce handlers that had previously been submitted to and evaluated by the agency.

The information in these comments is consistent with the agency's understanding of the use of sulfites, as discussed in the August 14, 1985, proposal (50 FR 32830). The information presented in these comments provides further evidence that voluntary efforts to discontinue the use of sulfites have not been fully successful, and that the use of sulfites on fresh fruits and vegetables is not being declared at the retail level. Consequently, this information provides further support for FDA's conclusion that it must find that this use of sulfites is not GRAS.

11. A trade association for the wine industry commented on the use of sulfites in wines even though this use is not the subject of this regulation.

Because the issues discussed in the comment deal specifically with wine, and have no direct bearing on the use of sulfites in fresh fruits and vegetables, FDA is not responding to this comment in this rulemaking. FDA will respond to these issues when it publishes a document addressing the safety of all other food uses of sulfites.

12. Thirty-eight comments addressed the use of sulfites in drugs.

Because the issues discussed in these comments deal specifically with the use of sulfites in drugs, and because FDA recently published a proposed rule addressing this use of sulfites (November 19, 1985; 50 FR 47558), FDA is not responding to these issues in this rulemaking. FDA has, however, included these comments in the public record on that proceeding and will respond to them when it publishes a final rule regarding the use of sulfites in drugs.

13. After the close of the official comment period, a trade association submitted a report regarding the prior sanction status of sulfiting agents in foods. The submitter purported to document the existence of prior sanctions for the use of sulfiting agents on many specific foods including fresh fruits and vegetables. The submitter stated that the report was intended for use by any party that might wish to assert prior sanctions for certain sulfite uses.

No party has chosen to assert a prior sanction in connection with this rulemaking. However, as stated in the proposal, the agency believes that if a prior sanction does exist for the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw, reliance on that sanction would not be sufficient justification to continue this use of sulfiting agents. While a prior sanction may exempt a substance from being a food additive under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), it does not exempt the substance from the adulteration provisions of the act. FDA believes that recent information demonstrates that this use of sulfiting agents may be injurious to a significant number of people, and that the use of sulfiting agents on fruits and vegetables intended to be served raw to consumers or sold raw to consumers would cause the food to be adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)).

III. Federal Advisory Committee on Hypersensitivity to Food Constituents

The phenomenon of allergic-type reactions to food ingredients presents numerous issues that are broader in scope than those that are the subject of this document. Thus, in the *Federal Register* of April 16, 1983 (49 FR 10521), FDA announced that the Secretary of the Department of Health and Human Services has established an ad hoc Advisory Committee on Hypersensitivity to Sulfiting Agents in Foods (now the Advisory Committee on Hypersensitivity to Food Constituents) to function under FDA's Center for Food Safety and Applied Nutrition. The committee is reviewing and evaluating

available information and data relevant to the adverse reactions in humans that are associated with food ingredients, including sulfiting agents. The committee will make appropriate recommendations to the Commissioner of Food and Drugs.

The committee met on December 12 and 13, 1985, to review specifically the available information on the use of sulfiting agents in food. The committee generally supported FDA's proposal to rescind the GRAS status of the use of sulfites on fresh fruits and vegetables (Ref. 1). However, it also encouraged FDA to include fresh potatoes in this action and to exclude fresh mushrooms and table grapes provided those two commodities comply with maximum residual levels of 10 parts per million total sulfur dioxide equivalents.

FDA has considered the recommendations made by the committee. Because the order set forth below addresses only the use of sulfiting agents in fruits and vegetables intended to be served raw or sold raw to consumers, the agency will respond here only to the recommendations regarding grapes and mushrooms. FDA will respond to the recommendation regarding potatoes in a future *Federal Register* document.

As noted in the proposal, the use of sulfiting agents on grapes is not included in this action. When used on grapes, sulfiting agents are used as a fungicide on a raw agricultural commodity. Therefore, this use is subject to regulation by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and not to regulation by FDA. FDA has provided EPA with a copy of the transcript of the committee's meeting of December 12 and 13, as well as copies of all information in FDA's files regarding this use. EPA has initiated its own review and evaluation of the safety of the use of sulfites on grapes.

FDA has evaluated the committee's request regarding fresh mushrooms in conjunction with other information on this use of sulfites that has been submitted to the agency. A mushroom trade association submitted information showing mushrooms, treated according to a procedure identified as standard industry practice, contain from 31 to 72 parts per million residual sulfur dioxide equivalents immediately after treatment, and that these levels do not drop below 10 parts per million until the mushrooms have been stored for at least 25 hours. The same comment also stated that research aimed at determining whether

these residual levels of sulfur dioxide are safe would be conducted.

FDA encourages such research, because, as stated above, available information is inconclusive as to whether there is a threshold level of sulfiting agents below which sulfite-sensitive individuals will not experience adverse reactions and as to how high that level might be. Until such information is forthcoming, FDA believes that it would not be in the public interest to exempt mushrooms from this regulation revoking the GRAS status of this use of sulfiting agents.

Moreover, data collected by FDA's Philadelphia District Office show that only 14 percent of the mushroom growers or distributors in Delaware and Pennsylvania were applying sulfites to fresh mushrooms in 1985 (Ref. 2). This area produces about 40 percent of the total U.S. production of fresh mushrooms and is generally regarded as likely to contain the highest number of growers or distributors that apply sulfites. Furthermore, producers who currently market clean mushrooms that have not been chemically washed state that certain inexpensive cultivating and harvesting techniques can be used as a substitute for sulfite washes. Thus, data show that the use of sulfite washes for mushrooms is not widespread and that adequate substitutes exist.

Therefore, the agency is not adopting the committee's recommendation regarding fresh mushrooms.

IV. Conclusion on Safety

After evaluating the issues and information presented in the comments on the proposal and all other available evidence, the agency has determined that a consensus does not exist that the use of sulfiting agents is safe in fruits and vegetables intended to be served raw or sold raw to consumers. As a result, FDA concludes that this use of sulfites can no longer be considered to be GRAS. Therefore, the agency is amending Part 182 to exclude the use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw to consumers, or to be presented to consumers as fresh, from the uses of sulfiting agents that are GRAS. The use of sulfiting agents on fruits and vegetables intended to be served raw or sold raw to consumers, or to be presented to consumers as fresh, would constitute the use of unapproved food additives and would, therefore, cause any food to which they have been added to be adulterated and in violation of section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)). Should someone claim that a prior sanction exists for this use of

sulfites, addition of sulfites to fruits and vegetables intended to be served raw or sold raw to consumers would still be illegal because it would render the food adulterated under section 402(a)(1) of the act.

V. Procedural Considerations

The agency has previously considered the environmental effects of this rule as announced in the proposal (August 14, 1985; 50 FR 32830). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

However, two comments did disagree with FDA's estimate of the economic impact of the regulation. One comment stated that FDA's economic impact estimate was too low. The other comment stated that the cost of revoking the GRAS status of the use of sulfites on fresh mushrooms would exceed \$14 million and would adversely affect a substantial number of small businesses.

Both comments also submitted data regarding the use of sulfites on fresh mushrooms. These comments stated that fresh mushrooms are rinsed in water containing sulfiting agents to eliminate any casing soil that might remain after harvest. In addition to providing the consumer with a product that is free of casing soil, this practice also allows producers to sell excessively soiled mushrooms in the fresh rather than the processed market. Recent price comparisons indicate that the price for fresh mushrooms is approximately \$.36 per pound more than the price for mushrooms that are to be processed (U.S. Department of Agriculture (USDA) 1984-1985 average price differential for the United States).

FDA has evaluated the information in these two comments and does not agree that the kind of impact estimated in the comments is likely. As discussed in Section III. of this preamble, the agency believes that the vast majority of fresh mushroom producers do not treat their mushrooms with a sulfite wash. Therefore, the loss of sulfiting agents will not result in a substantial diversion of mushrooms from the fresh to the processed market with an attendant decrease in revenue. Further, clean mushrooms that have not been chemically washed are currently marketed. Producers of these preservative-free mushrooms state that certain inexpensive cultivating and harvesting techniques can be used to produce a relatively soil-free mushroom.

Thus, the use of sulfiting agents by fresh mushroom growers is not universal, and an economic dependency on sulfiting agents for use on fresh mushrooms has not been demonstrated by current users. Consequently, FDA has determined that this regulation will not produce a major economic impact on fresh mushroom producers or a significant economic impact on a substantial number of small entities.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

VI. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Transcript, Ad Hoc Advisory Committee on Hypersensitivity to Food Constituents, December 12 and 13, 1985, meeting, pp. 359-363.
2. Memorandum from Paula J. Oliver, Director, Investigations Branch, Philadelphia District Office, FDA, to Sulfite Monitor, Center for Food Safety and Applied Nutrition, "Sulfiting Agents in Fresh Mushrooms," December 3, 1985.

List of Subjects in 21 CFR Part 182

Food ingredients, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 182 is amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 182 is revised to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended; 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.11.

2. In § 182.3616 by revising paragraph (c), to read as follows:

§ 182.3616 Potassium bisulfite.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

3. In § 182.3637 by revising paragraph (c), to read as follows:

§ 182.3637 Potassium metabisulfite.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

4. In § 182.3739 by revising paragraph (c), to read as follows:

§ 182.3739 Sodium bisulfite.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

5. In § 182.3766 by revising paragraph (c), to read as follows:

§ 182.3766 Sodium metabisulfite.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats or in food recognized as source of

vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

6. In § 182.3798 by revising paragraph (c), to read as follows:

§ 182.3798 Sodium sulfite.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in

meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

7. In § 182.3862 by revising paragraph (c), to read as follows:

§ 182.3862 Sulfur dioxide.

* * * * *

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing

practice, except that it is not used in meats or in food recognized as source of vitamin B₁, and that it is not used on fruits or vegetables intended to be served raw to consumers or sold raw to consumers or to be presented to consumers as fresh.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

Dated: July 11, 1986.

[FR Doc. 86-15391 Filed 7-8-86; 8:45 am]

BILLING CODE 4160-01-M