

other documents submitted to the Internal Revenue Service (an individual's social security number or an employer identification number) is not furnished. When payment is made in securities, a cash adjustment will be made to or required of the bidder for any difference between the face amount of securities presented and the amount payable on the securities allotted.

5.2. In every case where full payment has not been completed on time, an amount of up to 5 percent of the face amount of securities allotted, shall, at the discretion of the Secretary of the Treasury, be forfeited to the United States.

5.3. Registered securities tendered in payment for allotted securities are not required to be assigned if the new securities are to be registered in the same names and forms as appear in the registrations or assignments of the securities surrendered. When the new securities are to be registered in names and forms different from those in the inscriptions or assignments of the securities presented, the assignment should be to "The Secretary of the Treasury for (securities offered by this circular) in the name of (name and taxpayer identifying number)." If new securities in coupon form are desired, the assignment should be to "The Secretary of the Treasury for coupon (securities offered by this circular) to be delivered to (name and address)." Specific instructions for the issuance and delivery of the new securities, signed by the owner or authorized representative, must accompany the securities presented. Securities tendered

in payment should be surrendered to the Federal Reserve Bank or Branch or to the Bureau of the Public Debt, Washington, D.C. 20226. The securities must be delivered at the expense and risk of the holder.

5.4. If bearer securities are not ready for delivery on the settlement date, purchasers may elect to receive interim certificates. These certificates shall be issued in bearer form and shall be exchangeable for definitive securities of this issue, when such securities are available, at any Federal Reserve Bank or Branch or at the Bureau of the Public Debt, Washington, D.C. 20226. The interim certificates must be returned at the risk and expense of the holder.

5.5. Delivery of securities in registered form will be made after the requested form of registration has been validated, the registered interest account has been established, and the securities have been inscribed.

6. General Provisions

6.1. As fiscal agents of the United States, Federal Reserve Banks are authorized and requested to receive tenders, to make allotments as directed by the Secretary of the Treasury, to issue such notices as may be necessary, to receive payment for and make delivery of securities on full-paid allotments, and to issue interim certificates pending delivery of the definitive securities.

6.2. The Secretary of the Treasury may at any time issue supplemental or amendatory rules and regulations governing the offering. Public

announcement of such changes will be promptly provided.

Gerald Murphy,
Acting Fiscal Assistant Secretary.

[FR Doc. 82-17502 Filed 6-24-82; 3:34 pm]

BILLING CODE 4810-40-M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Implementation of Duty Concessions on Certain Television Receiver Components and Printed Circuit Boards

Import relief actions proclaimed in Presidential Proclamation 4634 of January 26, 1979, and extended by Proclamation 4769 of June 30, 1980 concerning color television receivers and certain subassemblies thereof will terminate on June 30, 1982. This relief included orderly marketing agreements and temporary quantitative limitations as to importations from Taiwan and the Republic of Korea. Therefore, pursuant to Section E of Annex IV to Proclamation 4707 of December 11, 1979, which provides that upon the termination of these import relief actions the staging of items 685.16 and 685.18 of the concessions granted during the Tokyo Round of Multilateral Trade Negotiations on imports of certain television receiver components and printed circuit boards, provided for in tariff schedules of the United States (TSUS) will be implemented. Accordingly, such implementation shall occur with respect to articles entered, or withdrawn from warehouse for consumption, in accordance with the following schedule:

TSUS item	Rate from which staged	Rates of duty, ¹ effective with respect to articles entered, or withdrawn from warehouse for consumption, on and after—							
		July 1, 1982	Jan. 1, 1983	Jan. 1, 1984	Jan. 1, 1985	Jan. 1, 1986	Jan. 1, 1987	Jan. 1, 1988	Jan. 1, 1989
658.16.....	5% ad val.....	4.8%	4.7%	4.5%	4.4%	4.2%	4%	3.9%	3.7%
685.18.....	5% ad val.....	4.8%	4.7%	4.5%	4.4%	4.2%	4%	3.9%	3.7%

¹The symbol "%" indicates percent ad valorem.

David R. Macdonald,
Deputy, United States Trade Representative.

[FR Doc. 82-17475 Filed 6-28-82; 8:45 am]

BILLING CODE 3190-01-M

Sunshine Act Meetings

Federal Register

Vol. 47, No. 125

Tuesday, June 29, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

CONSUMER PRODUCT SAFETY COMMISSION

TIME: 10 a.m., Wednesday, June 30, 1982.

LOCATION: Room 456, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

- Bicycle Brake Test Procedures*
The Commission will consider issues related to procedures for the testing of bicycle brake systems.

Closed to the Public:

- Compliance status Report
The staff will brief the Commission on compliance activities during the past month.

CONTACT PERSON FOR ADDITIONAL

INFORMATION: Sheldon D. Butts, Deputy Secretary, Office of the Secretary, Suite 342, 5401 Westbard Avenue, Bethesda, MD 20207; Telephone (301) 492-6800.

(S-948-82 Filed 6-25-82; 10:13 am)

BILLING CODE 6355-01-M

2

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

TIME AND DATE: 9:30 a.m. (eastern time), Tuesday, June 29, 1982.

PLACE: Commission Conference Room 5240, fifth floor, Columbia Plaza Office Building, 2401 E Street, NW., Washington, D.C. 20506.

STATUS: Part will be open to the public and part will be closed to the public.

MATTERS TO BE CONSIDERED: Open to the public:

- Ratification of Notation Vote(s).
- Freedom of Information Act Appeal No. 82-5-FOIA-32-SL, concerning a request for copies of documents contained in an ADEA complaint file.
- Freedom of Information Act Appeal No. 82-04-FOIA-056-MK, concerning a request for all information supplied to the EEOC by a respondent company.
- Freedom of Information Act Appeal No. 82-4-FOIA-21-NO, concerning a request for all materials relating to EEOC Charge No. 085-79-0057.
- Freedom of Information Act Appeal No. 82-3-FOIA-30-NY, concerning a request for witness statements and statistical analysis from an open age discrimination case file.
- Proposed Section 93 of the EEOC Compliance Manual.
- Proposed modification to an existing contract.
- Proposed contract for services needed in connection with a court case.
- State and Local Program: Recommended Mid-Year Modification of FY '82 New Charge Resolution Contracts.
- Proposed Principles of EEOC's Title VII Program for State and Local Fair Employment Practices Agencies for FY '83.
- Proposed Principles of EEOC's Program for State and Local ADEA Charge Resolution Contracts for FY '83.
- A Report on Commission Operations by the Executive Director.

Closed to the public:

Litigation Authorization; General Counsel Recommendations.

Note.—Any matter not discussed or concluded may be carried over to a later meeting.

(In addition to publishing notices on EEOC Commission Meetings in the Federal Register, the Commission also provides recorded announcements a full week in advance on future Commission sessions. Please telephone (202) 634-6748 at all times for information on the time, place and subject matter of such meetings.)

CONTACT PERSON FOR MORE

INFORMATION: Trava I. McCall, Executive Officer, Executive Secretariat, at (202) 634-6748.

This Notice Issued June 22, 1982.

(S-946-82 Filed 6-25-82; 8:45 am)

Billing Code 6570-06-M

3

FEDERAL COMMUNICATIONS COMMISSION

Open Commission Meeting, Thursday, July 1, 1982

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, July 1, 1982 which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street NW., Washington, D.C.

Agenda, Item No., and Subject

General—1—Title: In re General Docket 81-461 concerning request of General Electric Co. to exempt medical diagnostic equipment from Subpart J of Part 15 of the Rules of the Federal Communications Commission. **Summary:** This action considers adoption of an exemption for certain medical equipment from the computing device rules Part 15 Subpart J, which limit the interference potential of devices that employ digital electronics. A Notice of Proposed Rule Making in this proceeding was adopted July 16, 1981 and released September 8, 1981, in response to a petition filed by General Electric Co.

Private Radio—1—Title: Amendment of Parts 2 and 97 of the Commission's Rules to protect military areas by power limitation on Amateur radio stations operating in the 420-450 MHz frequency band. **Summary:** The Commission will consider whether to adopt an Order to extend to two additional military areas the 50-watt power limit; and to enlarge the restricted areas around two other military locations already specified.

Private Radio—2—Title: Notice of Proposed Rulemaking in the Matter of Amendment of the "Grandfathering" Provisions for Transmitter and Antenna Standards in Part 94. **Summary:** The FCC will consider whether to adopt a Notice of Proposed Rulemaking looking toward grandfathering, for an indefinite period, transmitting equipment (including antennas) which was authorized in the Private Operational-Fixed Radio Service prior to July 1, 1976.

Aural—1—Title: In re application of Ettlinger Broadcasting Corporation for a construction permit for a new FM station. **Summary:** The Commission considers a petition by Ettlinger Broadcasting Corporation, applicant for a new FM station at Westmorland, California for reconsideration of our *Memorandum Opinion and Order*, adopted July 18, 1980, denying its waiver request and dismissing its application.

Broadcast—1—Title: An Inquiry Relating to the Commission's Radio Operator Licensing Program. **Subject:** The Commission will consider action to be taken in response to petitions requesting reconsideration of rule amendments made by a *Fourth Report and Order* concerning the radio operator licensing program. Petitioners requested restoration of the First Class Radiotelephone License, and both clarification and deletion of certain amended rules.

Broadcast—2—*Title:* Notice of Proposed Rule Making in the Matter of Amendment of Section 73.1201(b)(2) of the Commission's Rules—Additional City Identification. *Summary:* The Notice proposes to change the Commission's procedures under which broadcast stations may seek permission to identify by communities in addition to their community of license.

Broadcast—3—*Title:* Memorandum Opinion and Order, In the Matter of Petition for Stay, or in the Alternative, Extension of Divestiture Deadline—Anniston Broadcasting Corporation. *Subject:* The Memorandum Opinion and Order considers and resolves the issues raised by Anniston Broadcasting Company in its petition for stay of a divestiture deadline. That deadline is applicable to Anniston as it is one of the 16 egregious cases identified in the Second Report and Order in Docket No. 18110 in which an existing newspaper/broadcast cross-ownership combination had to be severed.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Maureen P. Peratino, FCC Public Affairs Office, telephone number (202) 254-7674.

Issued: June 24, 1982.

William J. Tricarico,
Secretary, Federal Communications Commission.

[S-952-82 Filed 6-25-82; 3:18 pm]

BILLING CODE 6712-01-M

4

FEDERAL COMMUNICATIONS COMMISSION Deletion of Agenda Item From June 23rd Closed Meeting

The following item has been deleted at the request of the Broadcast Bureau from the list of agenda items scheduled for consideration at the June 23, 1982, Closed Meeting and previously listed in the Commission's Notice of June 16, 1982.

Agenda, Item No., and Subject

Complaints and Compliance—1—Field investigation into the operation of Station WABC-TV New York, New York.

Deletion of Agenda Item from June 23rd Open Meeting

The following item has been deleted at the request of Commissioner Dawson's office from the list of agenda items scheduled for consideration at the June 23rd Open Commission Meeting and previously listed in the Commission's Notice of June 16, 1982.

Agenda, Item No., and Subject

Aural—1—*Title:* In re application of Ettlinger Broadcasting Corporation for a construction permit for a new FM station.

Summary: The Commission considers a petition by Ettlinger Broadcasting Corporation, applicant for a new FM station at Westmorland, California for reconsideration of our *Memorandum Opinion and Order*, adopted July 18, 1980, denying its waiver request and dismissing its application.

Issued: June 23, 1982.

William J. Tricarico,
Secretary, Federal Communication Commissions.

[S-953-82 Filed 6-25-82; 3:18 pm]

BILLING CODE 6712-01-M

5

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 2:00 p.m. on Wednesday, June 30, 1982, to take up the following matter:

Petition of the Investment Company Institute seeking a public hearing and certain other relief in connection with the creation and operation by The Boston Five Cents Savings Bank, Boston, Massachusetts, of two wholly-owned subsidiaries to advise and distribute shares in a mutual fund.

In calling the meeting, the Board of Directors determined, by affirmative vote of Chairman William M. Isaac, Director Irvine H. Sprague (Appointive), and Mr. H. Joe Selby, acting in the place and stead of Director C. T. Conover (Comptroller of the Currency), that Corporation business requires it to take up the matter on less than seven days' notice to the public.

No earlier notice of this meeting was practicable.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389-4425.

Dated: June 25, 1982.

Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.

[S-955-82 Filed 6-25-82; 3:50 pm]

BILLING CODE 6714-01-M

6

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 9:30 a.m. on Thursday, June 24, 1982, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to make funds available for the payment of insured deposits in Citizens Bank, Tillar, Arkansas, which was closed by the Arkansas State Bank Commissioner on Wednesday, June 23, 1982.

In calling the meeting, the Board determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague, concurred in by Mr. William A. Longbrake, acting in the place and stead of Director C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matter on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matter in a meeting open to public observation; and that the matter could be considered in a closed meeting pursuant to subsections (c)(8) and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(8) and (c)(9)(B)).

Dated: June 24, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,
Executive Secretary.

[S-950-82 Filed 6-25-82; 11:50 am]

BILLING CODE 6714-01-M

7

FEDERAL MARITIME COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 47 FR 27447, June 24, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 9 a.m., June 30, 1982.

CHANGE IN THE MEETING: Addition of the following item to the closed session:

1. Petition of Seatrain Lines, Inc. for relief from recordkeeping and reporting requirements.

[S-951-82 Filed 6-25-82; 3:17 pm]

BILLING CODE 6730-01-M

8

FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Tuesday, July 6, 1982.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed extension of the reclamation authority of the Department of the Treasury.

2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

3. Any items carried forward for a previously announced meeting.

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board, (202) 452-3204.

James McAfee,

Associate Secretary.

[S-954-82 Filed 6-25-82; 3:32 pm]

BILLING CODE 6210-01-M

9

POSTAL SERVICE

Board of Governors Meetings

The Board of Governors of the United States Postal Service, pursuant to its Bylaws (39 CFR 7.5) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice that it intends to hold meetings at 2:00 p.m. on Tuesday, July 6, in San Francisco, California, and at 8:00 a.m. on Wednesday, July 7, 1982, in Classroom 4 in the Training Center of the Western Regional Headquarters Complex, 850 Cherry Avenue, San Bruno, California. As indicated in the following paragraph, the Tuesday afternoon session is closed to the public. The Board expects to discuss the matters stated in the agenda which is set forth below. Requests for information about the meeting should be addressed to the Secretary of the Board, Louis A. Cox, at (202) 245-4632.

At its meeting on June 7, 1982, the Board of Governors of the United States Postal Service voted to close to public observation its meeting scheduled for July 6, 1982, which is expected to be

attended by the following persons: Governors Hardesty, Babcock, Camp, Hughes, Jenkins, McKean, and Sullivan; Postmaster General Bolger; Deputy Postmaster General Benson; Secretary of the Board Cox; Counsel to the Governors Califano; Assistant Postmaster General Cummings; and Executive Assistant to the Postmaster General Coughlin.

The portion of the Board meeting to be closed will consist of a discussion of Postmaster Service strategic planning.

Agenda

1. Minutes of the Previous Meeting.

2. Remarks of the Postal General.

(In keeping with its consistent practice, the Board's agenda provides this opportunity for the Postmaster General to inform the members of miscellaneous current developments concerning the Postal Service. He might report, for example, the appointment or assignment of a key official, or the effect on postal operations of unusual weather or a major strike in the transportation industry. Nothing that requires a decision by the Board is brought up under this item.)

3. Report on the National Academy of Public Administration.

(The Board will consider the Academy's report on Postal Service progress under the Postal Reorganization Act.)

4. Capital Investment Project: Bakersfield, California General Mail Facility

(Mr. Caraveo, Acting Regional Postmaster General, Western Region, will present a proposal for a new General Mail Facility at Bakersfield, California.)

5. Postal Rate Commission Recommended Decision on Attached Mail Proceeding, 1981 and Attached Mail Rates, 1981 (Docket Nos. MC81-2 and R81-1)

(The Board will consider this Recommended Decision, by the Postal Rate Commission, dated June 15, 1982.)

Louis A. Cox,

Secretary.

[S-947-82 Filed 6-25-82; 9:53 am]

BILLING CODE 7710-12-M

10

SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 47 FR 26067, June 16, 1982.

STATUS: Closed meeting.

PLACE: Room 825, 500 North Capitol Street, Washington, D.C.

DATE PREVIOUSLY ANNOUNCED: Friday, June 11, 1982.

CHANGES IN THE MEETING: Additional item. The following item will be considered at a closed meeting scheduled for Thursday, June 24, 1982, following the 10:00 a.m. open meeting.

Settlement of administrative proceeding of enforcement action.

Chairman Shad and Commissioners Evans and Longstreth determined by vote that Commission business required consideration of this matter and that no earlier notice thereof was possible.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Paul J. Siegelbaum at (202) 272-2468.

June 24, 1982.

[S-949-82 Filed 6-25-82; 10:45 am]

BILLING CODE 8010-01-M

Food and Drug Administration

Tuesday
June 29, 1982

Part II

Department of Agriculture

Food Safety and Inspection Service

Standards and Labeling Requirements for
Mechanically Separated (Species) and
Products in Which It Is Used

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 318 and 319

[Docket No. 81-016 F]

Standards and Labeling Requirements for Mechanically Separated (Species) and Products in Which It Is Used

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture is amending the Federal meat inspection regulations to (1) modify the definition and standard (including parameters for measuring compliance) and permitted uses for the finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses and the labeling requirements for meat food products in which it is used as an ingredient and (2) establish a labeling requirement of such product.

This rule is based on data, information, and arguments accumulated by and submitted to the Department since the regulations for this product were promulgated on June 20, 1978, the Department's review and reevaluation of these regulations, and comments received in connection with the Department's July 31, 1981 proposal to modify these regulations.

EFFECTIVE DATE: July 29, 1982.

FOR FURTHER INFORMATION CONTACT:

Robert G. Hibbert, Director, Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-6042.

SUPPLEMENTARY INFORMATION:

Regulatory Impact Analysis

When proposed, this action was reviewed under USDA procedures established to implement Executive Order 12291 and classified as a major rule pursuant to section 1(b)(1) of that order because it is likely to result in an annual effect on the economy of \$100 million or more. The Department's preliminary review of its proposal was reported in its Preliminary Regulatory Impact Analysis (PRIA), which was published as an appendix to the proposal. The Department's review of its final rule is reported in its Regulatory Impact Analysis (RIA), which is available upon request from Robert G. Hibbert and is summarized below. The RIA also satisfies the analysis

requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*), which deals with the impact of regulation on small entities.

Purpose of the Amendments

The Department of Agriculture is amending the regulatory requirements for the finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses and for finished meat food products in which this product is used as an ingredient (9 CFR 317.2(j)(13), 318.18, 319.5, and 319.6 and Part 319). The purpose of these amendments is to facilitate the production and use of this product while continuing to fulfill the Department's statutory responsibility to prevent the preparation and distribution in commerce of meat and meat food products which are adulterated or misbranded or not properly marked, labeled, and packaged. See sections 1 (m) and (n), 7, and 10 of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 (m) and (n), 607, 610).

The regulations which have governed the production and use of this product, under the name "Mechanically Processed (Species) Product" ("MP(S)P"), were promulgated in the middle of 1978. 43 FR 26416. Very little of this product was produced after these regulations became effective, despite the availability of the technology and raw materials. As a result, a potential food source was not made available to the general public. The red meat industry contended that its failure to market products containing MP(S)P was due to regulatory requirements which go beyond what is necessary to protect the public, and it asked the Department to reconsider these requirements in light of additional information compiled since the completion of the prior rulemaking in 1978. In particular, the Pacific Coast Meat Association (PCMA), a regional trade association of meat packing and processing companies, and the American Meat Institute (AMI), a national trade association of meat packing and processing companies, submitted a petition on behalf of their members in February 1981 which argued that they "are effectively precluded from producing or marketing mechanically deboned beef, pork, or veal or lamb by the misleading labeling and the unreasonable compositional standards imposed by" §§ 317.2(j)(13) and 319.5(a) of the Federal meat inspection regulations (9 CFR 317.2(j)(13) and 319.5(a)). In support of their request that these regulations be amended, PCMA and AMI also submitted two types of

evidence to the Department: A report on a series of consumer focus group sessions exploring attitudes towards various types of meat food product labeling and an analysis of the economic impacts of the 1978 regulations.

Based on data, arguments, and information compiled since the completion of its prior rulemaking and its own review and reevaluation of the 1978 regulations in accordance with the principles of Executive Order 12291, and in view of the importance of taking advantage of all safe and wholesome sources of food, it appeared to the Department that certain of these regulations could and should be amended to facilitate the production and use of this product while continuing to protect the public against adulterated and misbranded products. Therefore, on July 31, 1981, the Department published a proposal to amend the Federal meat inspection regulations to (1) change the name of the product to one which appears to be less burdensome and more descriptive of its characteristics; (2) establish two categories of product: one which meets the current fat and protein content requirements, and a second as to which there are no fat or protein content requirements; (3) permit use of the second category of product only in meat food products subject to regulatory definitions and standards that limit fat content; (4) replace the limit on the amount of product meeting fat and protein content requirements which may be used with limits on the amount of calcium such product may contain (as a measure of its bone content) when it is used at various levels; (5) delete the requirement that the names of all meat food products containing the product must be qualified by a phrase indicating its presence, but consider retaining this requirement in particular situations on the basis of information submitted in this rulemaking; (6) replace the requirement that the names of meat food products containing the product must be further qualified to indicate the amount of powdered bone they contain with a requirement that their labels declare calcium content as part of a nutrition label—or, if a meat food product does not bear nutrition labeling, in a statement in immediate conjunction with the ingredients list—whenever the amount so declared would differ from the amount that would be declared if such meat food product contained only hand deboned ingredients; and (7) add labeling requirements for the product itself where this is necessary to assure compliance with the regulations. 46 FR 39274.

The proposal also reflected the Department's continuing belief that (1) the product differs materially from "meat" and should be subject to its own definition and standard and declared as a distinctive ingredient; (2) limits on bone particle size, bone content, and protein quality as well as handling controls and production under an approved quality control program are necessary to assure the product's safety and quality; and (3) use of the product should not be permitted in certain meat food products. However, the Department did propose additional minor changes in certain of the provisions embodying these requirements, primarily for purposes of clarification and simplification. 46 FR 39274, 39275.

The Department invited written comments on the proposal and the issues raised in its rulemaking notice for 90 days, until October 29, 1981. Since the publication of its proposal, the Department also has investigated further certain of the issues raised in its rulemaking notice. The information and analyses generated by this further investigation are reflected in documents in the record of this rulemaking.

After reviewing the comments submitted by the public in light of currently available information, the Department has determined that portions of the proposal should be adopted. Therefore, it is amending the Federal meat inspection regulations to (1) change the name of the product from "Mechanically Processed (Species) Product" ("MP(S)P") to "Mechanically Separated (Species)" ("MS(S)"); (2) establish two categories of product: one which meets maximum fat and minimum protein content requirements, and a second as to which there are no fat or protein content requirements; (3) permit use of the second category of product only in meat food products subject to regulatory definitions and standards that limit fat content; (4) delete the requirement that the names of all meat food products containing the product must be qualified by a phrase indicating its presence; (5) replace the requirement that the names of meat food products containing the product must be further qualified to indicate the amount of powdered bone they contain with a requirement that their labels declare calcium content as part of a nutrition label—or, if a meat food product does not bear nutrition labeling, in a statement in immediate conjunction with the ingredients list—where the product contributes 20 mg or more of calcium to a serving, unless the amount that would be declared would not differ from the amount that would be declared

if the meat food product contained only hand deboned ingredients or unless the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more if the meat food product contained only hand deboned ingredients; and (6) add a labeling requirement for the product itself in order to assure compliance with the regulations.

In addition, certain amendments are being adopted for the purposes of clarifying and simplifying these regulations. Finally, the Department has determined, based on currently available information, that it should not amend these regulations to permit MS(S) to constitute more than 20 percent of the livestock and poultry product portion of meat food products. Therefore, it is withdrawing the portion of the proposal that would have replaced this limit for product which meets maximum fat and minimum protein content requirements with limits on the amount of calcium such product may contain when it is used at various levels.

Historical Background

1. Interim Regulation and First Proposal

The regulations promulgated in 1978 were the result of a rulemaking that began on April 27, 1976 with the publication of a notice of proposed rulemaking titled "Definitions of Meat and Classes of Meat, Permitted Uses, and Labeling Requirements." 41 FR 17560. That proposed rulemaking included, among other things, a proposal for defining and permitting the manufacture of the following three types of product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle: "Mechanically Deboned Meat," "Mechanically Deboned Meat for Processing," and "Mechanically Deboned Meat for Rendering." Different nutritional parameters were proposed for the first two types of product. None were proposed for the third type, which, as such, was not to be used in the formulation of meat food products. No limit was proposed on the amount of the first type of product that could be used in finished products; and the second type was to be limited to 20 percent of the total meat, meat byproducts, poultry products, and poultry meat used in the formulation. The proposal also specified the meat food products in which these two types of product were to be permitted. There were more than 1,100 public comments on this proposal, a number of which raised various health and safety questions.

On April 27, 1976, an interim regulation that included standards for

the use of Mechanically Deboned Meat (MDM) also was published. This regulation was intended to be effective pending final rulemaking on the proposal, unless rescinded earlier. 41 FR 17535. The interim regulation was challenged by a coalition of various consumer oriented public interest groups, state officials, and a member of Congress in *Community Nutrition Institute, et al. v. Butz (CNI v. Butz)*, Civil Action No. 76-1585 (D.D.C., decided Sept. 10, 1976). The Court in *CNI v. Butz* held that the promulgation of the interim regulation was in violation of the Administrative Procedure Act and issued a preliminary injunction enjoining the Secretary from giving further effect to the interim regulation with respect to MDM.

In the Court's opinion, MDM was not "meat" as traditionally defined because of its bone particle content. Concluding that these bone particles must be regarded as a substance added during mechanical processing, the Court found that the Secretary had not considered adequately the health effects of MDM. The Court indicated that until these health questions were adequately assessed, MDM had to be considered as a substance which may injure health and, therefore, adulterated and an adulterant. In addition, it appeared to the Court that the interim regulation permitted misbranding because a product that contained MDM would have a higher calcium content than a comparable product without MDM. Since the public expects the "usual product", it would be misled by the labeling permitted by the regulation. This could prove especially harmful to persons on calcium-restricted diets, who would think that the product contained no more than the usual amount of calcium.

2. Panel Evaluation of Health and Safety Aspects

In order to respond to the health and safety questions raised by the Court, the Department initiated an analytical program to develop data on the amounts of nutrients and substances of concern which might be present in MDM. To evaluate findings from this analytical program and pertinent information and data gathered from other sources, an interagency panel of Government scientists was convened. This Panel consisted of experts in a wide range of subject areas dealing with health and safety aspects of food. The Panel was asked to respond to questions which had been raised by the Court, questions in the comments that had been filed on the proposed rulemaking, and other

issues which became evident during its deliberation.

The Panel's conclusions and recommendations were published in the reports titled "Health and Safety Aspects of the Use of Mechanically Deboned Meat, Volume I-Final Report and Recommendations, Select Panel" and "Health and Safety Aspects of the Use of Mechanically Deboned Meat, Volume II-Background Materials and Details of Data." The final report basically consists of a series of subcommittee reports, which were authored by persons having special expertise in the various subject fields and unanimously accepted by the Panel as a whole, and the conclusions and recommendations of the Panel. Both volumes were made available to the public in connection with the Tissue from Ground Bone proposal discussed below. 42 FR 54437, 54439; 43 FR 26416, 26417.

The following are the Panel's conclusions and recommendations, as supplemented by certain of the subcommittees' findings:

A. Bone particle size as obtained with mechanical deboners currently available presents no hazards to health. It seems likely that the bone particles will be dissolved by the stomach acid and provide an additional source of calcium. Non-digested particles, if they occur, will provide additional "bulk" to the diet, which is considered to be beneficial. However, the Panel recommended that limits for maximum particle size be included in any regulation to be promulgated allowing the preparation in commerce of MDM. The subcommittee believed it desirable to institute quality control measures to limit particle size to those levels presently associated with good manufacturing practice.

B. A slight nutritional benefit is to be expected for most people from the calcium in MDM, especially for persons whose customary intake of calcium falls below the Recommended Dietary Allowance. The calcium which would be added to the diet by MDM is not so great in amount as to pose a hazard to the health of most people except for those persons who are hyperabsorbers of calcium and likely already to be under medical supervision to limit their calcium intakes. The subcommittee suggested appropriate labeling to indicate that meat food products contain calcium so that the small percentage of the population which may require a low calcium intake for medical reasons would have the choice to avoid purchasing them.

C. The fluoride content of MDM poses no health problem for adults. Fluoride

intakes of children need to be controlled more closely than intakes of adults in order to avoid mottling of teeth. Since little is known about the fluoride intake of children, caution is advised. Data on projected consumption of MDM show that intakes of fluoride from MDM would be negligible, even for children consuming much higher than average quantities of MDM with a high fluoride content. MDM in the Panel's judgment presents no problem for children. However, fluoride intake of infants is known to be high. The Panel, therefore, concluded that prudence dictates that MDM not be incorporated into baby and junior foods at present. This recommendation was based primarily on lack of information rather than evidence of a hazard and should be subject to further evaluation as data are gathered. Long term data on the fluoride content of MDM are not available at present, and the fluoride content of MDM may vary in different localities and may also depend on the age of the cattle used.

D. The Panel concurred with its subcommittee's evaluation that, based on currently available data and relative to the magnitude of other environmental sources of lead, the amount of lead which would be provided by MDM is toxicologically insignificant for children and adults.

E. Amounts of cadmium in MDM are so small as to be not detectable by current analytical procedures and are of no public health significance.

F. Selenium was judged not to be a health problem. There is no evidence to indicate that selenium concentrates in bone.

G. Increases in dietary intakes of strontium-90 from use of MDM would be negligible, amounting to about a 1 percent increase in exposures which are already well below tolerable limits. MDM poses no health hazard in regard to strontium-90.

H. Cobalt, copper, iron, nickel, zinc, arsenic, and mercury pose no potential problems in relation to use of MDM. Consumption data indicate that MDM would probably provide about 1 percent of the expected daily intake of cobalt. Additional iron from MDM would be in the order of 2.5 percent of the total iron intake and should be readily available to the body. Zinc content of MDM is essentially the same as zinc in hand deboned meat, and use of MDM should not affect bioavailability of zinc from other dietary sources. Arsenic has not been found in mechanically deboned poultry, and poultry would be expected to have greater relative intakes of arsenic than red meat animals. Therefore, arsenic should present no

problem in MDM. Mercury does not accumulate in bone.

I. Chlorinated hydrocarbon residues present no special problem in MDM because if present in measurable amounts, they are found in quantities well below established tolerance or action limits.

J. Data presently available on the lipid spectrum of MDM show that it is comparable to the lipid pattern found in hand deboned meats. Available data, while limited, did not suggest that use of MDM will lead to any appreciable increase in dietary cholesterol or other lipids thought to be involved in pathological states in humans as compared with the consumption of other meat food products with similar fat contents; and no relationship between cholesterol content and total lipids content was observed. However, because of concern over the general problem of excessive intakes of fat and their effect on health, the Panel recommended that limits be placed on the fat content of MDM, on the basis of good manufacturing practices, and that limits also be placed on the fat content of products in which MDM could be used.

K. Proposed standards for protein content and quality (PER) are reasonable. Efforts should be continued to find more rapid and economical methods for monitoring protein quality to replace the cumbersome PER assay.

L. The microbiology of MDM presents no unique hazards and should not be a problem if good manufacturing practices and quality control programs are employed.

M. Tetracyclines accumulate in the bones of young animals, and a recent German study has found tetracyclines in calf bones. The amounts are such that even at the highest level found, residues in products made with MDM derived from calf bones likely would be within present permitted tolerances. The U.S. slaughters comparatively few calves, and it is unlikely that there will be calf MDM. Tetracyclines in older cattle and swine present no problem. Though it is apparent that the use of tetracyclines in calves is on the decline in the United States, controls should be established to assure that if MDM is prepared from calves, it will not exceed established tolerances for such drugs. (Mechanically Processed Veal Product (MPVP), the product referred to as "calf MDM" in the health and safety report, has, in fact, been produced in limited amounts since the promulgation of the 1978 regulations. In 1979, MPVP was being produced by a small establishment that is no longer in business. The Department collected and

analyzed three samples of this firm's product. Antibiotic residues were not detected in any of these samples. As of 1981, another firm was producing MPVP in small volume. Therefore, the Department established a sampling program to alert it if any tetracycline residue problem developed. After analysis of 12 samples, no antibiotic residues were detected in the samples collected under this program.)

N. The Panel agreed that MDM contained in food products should be so labeled in the ingredients statement so that persons who must stringently restrict calcium intake could avoid these products. The Panel further agreed that there was no need for health or safety reasons to make nutrition labeling mandatory for products containing MDM, although nutrition labeling of all food products should be encouraged.

O. The Panel recommended that efforts should be made to inform and educate health and medical professionals and the general public about dietary effects of use of MDM, especially in relation to calcium and fluoride.

P. The Panel recommended that further research should be encouraged on MDM when it is again produced commercially. Suggestions for research are given in several of the subcommittee reports.

3. Revised Proposal and Promulgation of a Final Rule in 1978

As a result of the Panel's conclusions and recommendations, *CNI v. Butz*, and the widespread public interest in and concern about this product, a revised proposal was published on October 6, 1977. 42 FR 54437. This proposal included the following changes from the original proposal:

(1) The product would be named "Tissue From Ground Bone" (TFGB) and would be labeled "Tissue From Ground (Species) Bone" in the ingredients statement. The name of the processed product in which it was used would be qualified by the term "Tissue From Ground (Species) Bone Added."

(2) The product would be classified as a meat food product rather than as a class of meat.

(3) The number of classes of this type of product would be reduced from three to one. "Mechanically Deboned Meat" and "Mechanically Deboned Meat for Processing" would be combined because the single use limitation for TFGB would make separate classes unnecessary.

(4) The product would be limited to 20 percent of the total of all meat, meat byproducts, poultry products, and poultry meat used in a processed product.

(5) The product could not be used in baby (strained), junior, or toddler foods.

(6) The calculation of percent of essential amino acids would be in terms of total amino acids rather than in terms of total protein; and data on the essential amino acid tryptophan would be excluded in making this calculation.

(7) The size of the openings of any screens, sieves, or ports used in preparing TFGB could be no greater than 0.5 millimeter in diameter.

(8) The requirements for minimum protein and maximum fat would be set at 14 and 30 percent, respectively.

The Department received 4,537 comments on this proposal, including presentations made at a February 14, 1978 public hearing. More than four-fifths of these comments were from consumers. Significant numbers of comments were also received from industry members (including meat packers, machinery and equipment companies, food processors, food wholesalers, retail organizations, and trade groups), academia (including university faculty and students and high school teachers), professionals (including physicians, dentists, veterinarians, dietitians, attorneys, and food managers), farmers and farm-related organizations, and government agencies.

The Administrator of the Food Safety and Quality Service (FSQS, the predecessor of FSIS) reviewed these comments and, among other things, made the following determinations as regards safety concerns: (1) The amount of calcium in the product should not exceed 0.75 percent. (2) Ingestion of bone particles from the product will not cause mechanical injury. (3) In view of all of the information available, with the addition of special processing and storage requirements, the product is wholesome and safe for use in products other than baby, junior, and toddler foods.

The Administrator agreed with comments that the proposed name, "Tissue From Ground Bone" ("TFGB"), could be misleading as the product contains both meat and bone, including bone marrow, and "TFGB" would incorrectly indicate that it is made wholly from parts of bone. He considered other proposed names and determined not to adopt "Mechanically Deboned Meat" because "deboned" would incorrectly represent that the product does not contain bone or bone marrow and "meat" would incorrectly represent that the product consists solely of "meat". The Administrator went on to conclude that the product should be named "Mechanically Processed (Species) Product", noting

that the term "product" includes any substance from livestock which is capable of use as human food (9 CFR 301.2(ww)). As regards labeling, the Administrator concluded (1) since MP(S)P is unique and would not be an expected ingredient, a qualifying statement should be added to finished product names to indicate its presence; (2) the need of some individuals to limit their intake of calcium is an important consideration and, therefore, finished product names should bear the additional qualifying statement, "Contains Up To —% Powdered Bone"; and (3) MP(S)P should be listed separately from "meat" in its order of predominance by weight in the ingredient statements of finished products because MP(S)P is not meat and it would be a standardized product following publication of the rule.

The proposed requirements for minimum protein content and protein quality and maximum fat content were retained in order to assure a standardized product of high nutritional quality which could be used in a wide range of finished products. Among other things, the Administrator could not agree with comments that the protein content minimum would severely restrict the kinds of materials that could be used in preparing the product based on the information available to the Department. The Panel's reluctance to approve a product that would increase the total fat composition of meat products was noted, as well as the fact that there are not limitations on the fat content of a number of products in which MP(S)P is a suitable ingredient.

The Administrator also concluded that, in order not to discourage the development of different types of processing equipment, the proposed limit on the size of openings in the equipment through which the product is strained would be replaced with a limit on the size of bone particles that would result from use of the proposed procedures. In addition, the Administrator agreed with comments that special requirements are needed to assure that establishments formulate MP(S)P to comply consistently with the regulatory requirements and thereby avoid false or misleading labeling. Therefore, the utilization of an approved quality control program was made a prerequisite to label approval and analytical requirements were specified.

As regards proposed restrictions on how the product could be used, the Administrator determined that (1) the 20 percent use limit is optimum in that it allows for the use of MP(S)P without diminishing the quality and overall

expected characteristics of products in which it is permitted and does not result in any health or safety problems; and (2) permitting MP(S)P to be used in certain products is not warranted and would violate consumers' expectations about those products. In response to concerns about economic aspects of the use of MP(S)P, it was noted that labeling requirements would enable consumers to make cost comparisons between products containing and products not containing MP(S)P and that certain of the objections were not relevant to whether MP(S)P should be produced and distributed because the Administrator has no authority to prohibit the production of wholesome, unadulterated, and properly labeled products.

In view of the Panel's findings and the views, data, and information available to the Department, and being mindful of the need for increasing food supplies and reducing waste of available proteinaceous nutritive materials, the Administrator concluded that production of MP(S)P should be allowed with the restrictions being imposed and amended Parts 317, 318, and 319 of the Federal meat inspection regulation (9 CFR Parts 317, 318, and 319) accordingly.

4. PCMA Petition

In April 1979, 9 months after these regulations became effective, the Pacific Coast Meat Association (PCMA), a regional trade association of meat packing and processing companies, petitioned the Department on behalf of its members and an ad hoc group of companies "which are effectively precluded from mechanically deboning beef, pork and veal by the negative labeling and unrealistic standards required by USDA regulations." PCMA requested that the Department (1) amend § 317.2(j)(13) of the regulations (9 CFR 317.2(j)(13)) by deleting the requirement that names of products containing MP(S)P be qualified to indicate the presence of that ingredient and by replacing the requirement that they be further qualified with a statement of powdered bone content with a declaration of calcium content either in the ingredients statement or as part of nutrition labeling and (2) amend § 319.5(a) of the regulations (9 CFR 319.5(a)) by deleting the minimum protein and maximum fat content provisions of the MP(S)P standard and leaving applicable the general fat to lean ratio requirements that apply to meat trimmings.

PCMA stated that, based on data available to it, only 898,749 pounds of MP(S)P had been produced in the 7 months following publication of the

regulations (17,040 from swine, 610,959 from cattle, and 270,750 from other sources, apparently calves), despite an investment in equipment of approximately \$30 million by approximately 40 meat packers and processors; and the very few MP(S)P-containing products on the market are sold almost entirely to institutions, not retail consumers. (Data from the Department's meat inspection program indicate that approximately 2.3 million pounds of MP(S)P were produced in fiscal year 1979 and approximately 2.0 million pounds were produced in fiscal year 1980.) PCMA argued that the MP(S)P regulations should be changed immediately because (1) the failure to recover this product results in unnecessary additional consumer expenditures of \$1 billion to \$3 billion for meat and meat products and raises the price of all beef and pork cuts at least 3 to 4 cents per pound, (2) competitive poultry products without restrictive labeling and standards have gained significant marketplace acceptance, (3) the MP(S)P labeling provisions create misleading connotations of inferiority, and (4) the MP(S)P labeling and standards provisions are not supported by comments in the rulemaking record.

To support its contentions regarding economic impact, PCMA appended an economic evaluation that it had commissioned from Dr. Willard F. Williams, Professor of Agricultural Economics, Texas Tech University. Among other things, Dr. Williams estimated that existing machinery could produce 99 million pounds of MP(S)P per year (77 million from cattle and 22 million from swine). As regards labeling requirements, PCMA argued that (1) MP(S)P will virtually never be the most prominent ingredient in a product, the name MP(S)P is legalistic and unfamiliar to consumers, and consumers associate prominent legalistic label declarations with negative health implications; and (2) the powdered bone content declaration erroneously implies that this residue is detrimental to consumers, and it does not address the nutritional issue (sensitivity to calcium) raised by the Panel. PCMA also cited rulemaking comments opposing the minimum protein and maximum fat content requirements and argued that (1) the only feasible controls on fat composition are regulation of the end product and consumer taste preferences and (2) restrictions on ingredient composition only limit blending, a process which benefits consumers economically by allowing access to the most reasonably priced ingredients. Finally, PCMA

contended that the review and approval of the health and safety aspects of MP(S)P during rulemaking and the huge inflationary impact of existing regulations make expedited rulemaking under 5 U.S.C. 553(b), without notice and comment procedure, appropriate.

The Department could not find sufficient grounds in PCMA's petition for granting the relief requested and, therefore, denied the petition in May 1979. PCMA was informed that while the Department does not want effectively to bar the marketing of any safe product or to inhibit the use of any process that may reduce industry costs and consumer prices, Dr. Williams' study did not support the petitioner's claims about the effects of current regulations. A copy of the Department's Economics, Statistics, and Cooperative Service's (ESCS's) review of the study was enclosed with the denial. The Department also indicated it was open to a resubmission of the PCMA's arguments with compelling evidence on (1) the effects on consumer preference of the current regulation and the amendments proposed by PCMA, (2) the economic effects of widespread use of MP(S)P, (3) industry's capability of producing and utilizing MP(S)P, and (4) whether the labeling proposed by PCMA would be false or misleading to any purchasers. The Department emphasized that the use of MP(S)P presents substantial problems of consumer understanding and education, citing the test for labeling set out in *Federation of Homemakers v. Hardin*, 328 F. Supp. 181 (D.D.C. 1971), *aff'd*, 466 F.2d 462 (D.C. Cir. 1972), and affirming the Department's belief that the current labeling provides information necessary for informed choice and is the best available alternative given present knowledge.

In June 1979, PCMA resubmitted its request along with a further explanation of its position, Dr. Williams' comments on ESCS's review, and a response to the comments on the petition which had been submitted by the Community Nutrition Institute. Because the resubmitted petition presented no new evidence, the Department denied it in September 1979. PCMA was informed that until further evidence was submitted to alter the conclusions in the original denial, the Department believed that they continued to be valid.

5. PCMA-AMI Petition

In the middle of 1980, PCMA and the American Meat Institute (AMI), a national association of meat packing and processing companies, informed the Department that they were compiling

information of the types to which the Department has referred in denying PCMA's 1979 petition. They submitted reports on the results of their efforts on February 11, 1981, along with a petition on behalf of their members to amend what they consider to be misleading labeling and unreasonable compositional requirements for MP(S)P which effectively preclude their members from producing or marketing various types of this product (beef, pork, veal, and lamb). Specifically, the PCMA-AMI petition requested that the Department (1) designate the ingredient resulting from the mechanical separation of meat from bone as "Mechanically Deboned Meat" ("MDM") because this name is clearer and more understandable to consumers than "Mechanically Processed (Species) Product" and it is the common or usual name by which the ingredient is known in the United States, (2) require that the presence of MDM be declared only in the ingredient statement, consistent with the general requirements for listing ingredients by their common or usual names in descending order of predominance (9 CFR 317.2(c)(2)), and delete the requirement that its presence be indicated in a phrase qualifying the names of meat food products in which it is used (9 CFR 317.2(j)(13)), (3) require a declaration of calcium content in the ingredient statement or as part of any nutrition label where the quantity of calcium in the meat portion of a meat food product is a nutritionally significant portion of the Recommended Daily Allowance (RDA) in lieu of the requirement that the names of meat food products be further qualified to indicate the amount of powdered bone they contain (9 CFR 317.2(j)(13)), (4) limit the total calcium content of the meat portion of a meat food product to no more than 1/4 percent in lieu of the present provision limiting use of MP(S)P to no more than 20 percent of the meat portion of any meat food product (9 CFR 319.6(b)), as a technology-forcing feature providing an incentive to lower powdered bone content, and (5) delete the minimum protein and maximum fat specifications in the product definition and standard (9 CFR 319.5(a)). The petition also recommended that the Department reexamine its limits on bone particle size (9 CFR 319.5(a)) in reference to proposed Canadian requirements and requested that the wording of the regulations be changed to substitute "Mechanically Deboned Meat" for the meat food product called "Mechanically Processed (Species) Product" (9 CFR Part 319).

PCMA and AMI stated that in view of the fact that meat packers and processors have invested approximately \$30 million in equipment, one can only conclude that the limited production of MP(S)P—less than 1 percent of the potential supply—is attributable to the unreasonably restrictive compositional and misleading labeling requirements; and they cited press reports of statements by the former Assistant Secretary of Agriculture for Food and Consumer Services and the former Associate Administrator of FSQS as indicating that the Department had reason to believe the burdensome nature of the present MP(S)P regulations requires a change. The petitioners believed that their proposed changes would have an extraordinarily positive environmental impact by making hundreds of millions of pounds of additional meat available with no added burden on agricultural production, by providing supplemental calcium, a needed nutrient, and by causing a huge conservation of valuable food resources. They also concluded that stifled production under existing regulations has had an inflationary impact on meat prices and is costing U.S. citizens more than \$500 million per year, and that their proposed modifications can remedy these effects without sacrificing any health or economic benefits provided by the current regulations.

As noted above, when the Department denied PCMA's 1979 petition, it indicated its willingness to reconsider the arguments raised therein if additional information in various areas were presented. In response, PCMA and AMI based their petition on the following evidence, as well as the experience gained in the 32 months since the promulgation of the MP(S)P regulations: (1) "Consumer Focus Groups Concerning Mechanically Processed Meat Product," a September 1980 report by Market Research Services, Chicago, Illinois, on a qualitative market research study which was commissioned by PCMA to provide information regarding consumer preferences and perceptions (what the current label means to them, how they feel about it, and how they feel about the product) and (2) "Economic Impacts of Regulations on Mechanically Deboned Red Meats," a July 1980 report by J. Bruce Bullock and Clement E. Ward, Associate Professors, Department of Agricultural Economics, Oklahoma State University, an AMI-supported economic analysis, the objectives of which were to identify the nature and estimate the dollar value of the economic contribution that red meat

mechanical deboning technology can have on the U.S. economy, to identify the nature of the economic impacts of regulations restricting production to less than economically feasible levels and estimate the economic costs of current regulations, and to develop information for determining the type of regulations (if any) needed to provide consumers with adequate information about the mechanically deboned red meat ingredient without preventing use of the efficiency-increasing technology.

Market Research Services reached the following conclusions on the basis of 8 focus group sessions lasting 1 1/2 to 2 hours each and including a total of 69 women aged 25 to 54 from middle income households (\$15,000 to \$30,000) in 4 metropolitan markets (Chicago, Los Angeles, Atlanta, and Washington) who reported doing most of the grocery shopping for their households and frequent use of many types of processed meat products:

(1) The term mechanically processed beef product is confusing to consumers, and it fails to adequately inform them as to what the product MPBP actually is.

(2) Most consumers reacted negatively to the emphasis of powdered bone (even in very small amounts) on a product label.

(3) It appears that consumers probably will not purchase products containing MPBP if labeled according to the 1978 USDA regulation.

(4) Mechanically deboned (beef) appears to be a more favorable and informative term than mechanically processed (beef) product.

(5) Once they know that MPBP actually is beef that has been mechanically deboned, most consumers believe it is unnecessary to emphasize the mechanical deboning process if, in fact, the product is safe and nutritious. Consumers do feel strongly, however, about listing all the product ingredients in the ingredient statement. (Underlining deleted.)

Market Research Services also cautioned that their research is exploratory in nature and their findings must be seen as hypotheses which are not intended to be projectable to any larger population.

PCMA and AMI stated that Market Research Services' conclusions should be read together with quantitative research prepared for the Gerber Products Company and previously submitted to the Department, which they believed confirms consumers' negative reactions to the format and content of existing labels for products containing MP(S)P. PCMA and AMI asserted that these materials should satisfy the

Department's request that compelling evidence regarding the effects of present and proposed regulations on consumer preference and whether the proposed labeling would be false or misleading to purchasers of the product accompany a resubmission of PCMA's arguments. PCMA's and AMI's arguments reflected the following positions: (1) "Mechanically Deboned Meat" is the common or usual ingredient name long used in the United States. (2) MDM is skeletal meat. Small and safe quantities of powdered bone do not decharacterize the ingredient's fundamental nature as "meat". Therefore, MDM as an ingredient is properly identified in the ingredient statement and requires no prominent qualifying phrase. (3) The powdered bone disclosure was required to provide information on calcium, a nutrient of which most consumers need more but intake of which some consumers should restrict. Consumers concerned about calcium content are best served by express information about calcium in the ingredient statement or, where nutrition labeling is used, in that labeling; however, such information should only be required where the amount of calcium is nutritionally significant.

The petitioners contended that the responses of the focus group participants support these positions. PCMA and AMI reported that the participants responded in an informed way to "Mechanically Deboned Meat", but were totally confused by the prominent qualifying phrase "Mechanically Processed Beef Product", that they found the word "processed" to be meaningless, that they found the word "product" to be confusing, and that they were immediately able to understand the term "Mechanically Deboned Meat" as meaning meat separated from bone by a mechanical means. PCMA and AMI also reported that the prominence given to the qualifying phrase indicating the presence of MP(S)P confused the focus group participants, arousing unwarranted apprehensions about a problem with the product without conveying information. In addition, PCMA and AMI reported that after the focus group participants learned that MPBP is beef that has been mechanically deboned, most believed it is unnecessary to emphasize the mechanical deboning process so long as the ingredient is safe and nutritious and it (like all product ingredients) is identified in the ingredient statement. Finally, the petitioners reported that the focus group participants found the powdered bone content declaration

derogatory and misleading (with many mistakenly thinking it referred to a separately added powdered bone ingredient and others mistakenly thinking detectable or hazardous hard pieces of bone would be present) and that they did not relate it to the presence of calcium.

Drs. Bullock and Ward studied the potential demand and supply for beef and pork product produced by mechanical deboning, the economic value of the mechanical deboning technology, the economic costs and benefits of regulations, and the potential impact of the mechanical deboning technology on livestock prices. They used published information and information from a mail survey of meat packers and processors who have commercially produced or experimented with beef and pork product produced by mechanical deboning as well as industry contacts to look at the potential economic effects of removing the requirements for phrases qualifying the names of finished products and for fat and protein content. Their analysis assumed that, as USDA's evaluation of health aspects indicates, there are no harmful effects of consuming this product; and while this may not be true for individuals who must restrict their calcium intake, the contents portion of the label will contain enough information to allow these individuals to avoid consuming the product in unhealthy amounts, and the number of such individuals is small and will have a negligible impact on the demand for processed meat food products containing this product. Their analysis also assumed that, as evidenced by consumers' ready acceptance of mechanically deboned poultry and fish products plus the growing production of MDM prior to the imposition of labeling restrictions, consumers will readily accept this product as an ingredient in processed meat food products at prices that provide an adequate incentive for its production and use.

Drs. Bullock and Ward reached the following conclusions:

Current MDM regulations generate social costs in the neighborhood of \$513 million per year. Benefits generated by the regulations are limited to a small segment of the population who must restrict their intake of calcium. An alternative regulation requiring the product label to contain information about the calcium content would generate the same benefits as the current regulations without generating social costs associated with those regulations.

(Their) analysis indicates that the following changes in MDM regulations would be in the public interest.

1. Revise product labeling requirements so that labels do not impede sales of MDM. The

revised label probably should include information about the calcium content of the final product for calcium sensitive consumers. This modified labeling regulation would generate the same social benefits but avoid the social costs of the current regulations.

2. Removal of the current regulations regarding fat, protein, and calcium contents of MDM. Existing regulations insure that meat products such as franks and weiners will not exceed specified fat levels. Establishing upper limits on the fat content of MDM provides the consumer with no more protection than existing regulations. Therefore, current regulations prevent processors from making efficient use of existing resources. The fat restriction will prevent a large portion of the potential raw material from being used in MDM production. The * * * analysis indicates that modification of the product labeling regulations without also removing the fat restrictions would remove less than 30 percent of the social costs associated with the current regulations.

3. The current regulations limiting the content of MDM in final products to no more than 20 percent of the meat ingredients does not appear to be generating social costs at the present time. However, there is no economic justification for this type of regulation. The success of a processed meat product in the marketplace depends on repeat purchases of satisfied customers. The rigors of the marketplace will weed out products that contain too much MDM to satisfy consumers. While this regulation is not generating social costs at the present time, it might do so in the future. Continuation of the 20 percent limit on MDM content would preclude development of potential new products that might be quite acceptable to consumers. Hence, the public interest would be served by removing this regulation.

PCMA and AMI stated that the Bullock and Ward study, as well as previous analyses and submissions, responded to the Department's request that additional information regarding the economic effects of widespread use of mechanically processed meat and industry's capability of producing and utilizing the product accompany a resubmission of PCMA's arguments. The petitioners asserted that while the methodology and conclusions regarding the aggregate dollar value of benefits in the analysis by Bullock and Ward and earlier analyses (cited in the petition) by Willard Williams and D. W. McNiel differ, each study concludes that modified regulation would result in substantial benefits and Bullock and Ward suggest that full benefits can occur within 2 years. Finally, PCMA and AMI relied on Bullock and Ward study as showing that the existing fat and protein content requirements are at least as limiting as the present labeling requirements and, therefore, as

supporting the petitioners' position that they should be deleted as limits on this ingredient and, if appropriate, should be imposed only on finished products.

6. Proposal to Amend 1978 Regulations

The Department reviewed the PCMA-AMI petition and accompany reports and it carefully considered the arguments raised therein in conjunction with other information it had accumulated over the past several years. The Department's review included the development of a Preliminary Regulatory Impact Analysis (PRIA) which, among other things, evaluated the economic analysis by Drs. Bullock and Ward. The Department also evaluated Market Research Services' report on a series on consumer focus group sessions. As transcripts or tapes of Market Research Services' focus group sessions were not submitted with the PCMA-AMI petition, the Department had not been able to verify the conclusions drawn in the report on this research at the time the proposal was published. Therefore, references to this research reflected the information then available and Market Research Services' evaluation of the data.

Based on its review and analysis, the Department decided to respond to the PCMA-AMI petition as part of a rulemaking which proposed changes in certain of the provisions in the 1978 regulations and sought comment regarding the issues raised by these proposed changes and other provisions. The Department's proposal was published on July 31, 1981. 46 FR 39274. The comment period ended 90 days later, on October 29, 1981.

After the publication of its proposal, the Department consulted its advisory committee on meat and poultry inspection regarding this matter, and it investigated further certain of the issues raised in the rulemaking notice. A transcript of the advisory committee's November 12-13, 1981 meeting has been placed on the record of this proceeding. In addition, documents reflecting the information and analyses generated by the Department's further investigation have been placed on that record. These documents include an analysis of additional data on the relative cholesterol, purine, and nucleic acid contents of products made by mechanically deboning livestock and meat. They also include an evaluation of Market Research Services' report on the consumer focus group research it conducted along with videotapes of the sessions themselves and transcripts of six of the eight sessions. As the evaluation indicates, the Department has concluded that Market Research

Services' report is a reasonable interpretation of the research as utilized in this rulemaking.

The Department received 1,604 comments that were postmarked on or before October 29, 1981, the close of the comment period. Nine hundred and fifty-seven of these comments were submitted by individual consumers. Three hundred and ninety-seven of these individuals identified themselves as being employees or relatives of employees of meat or poultry industry members as well as consumers. Five hundred and ninety-one of the comments came from industry-related individuals and groups: Meat and poultry industry members (individual producers, packers, and processors), their trade associations and organizations, equipment manufacturers and distributors, and 2 trade associations of food wholesalers. Sixteen of the comments from meat and poultry industry members and organizations endorsed, in whole or in part, the comments of trade associations or organizations. Of the 1,548 comments in these two categories, 902 were various form letters. While the specific positions taken in these letters varied, they all supported modifying the existing regulations to facilitate production and use of this product. The remaining 56 comments were submitted by a public interest organization, academia (including university faculty and students), other professionals (including physicians, dietitians, nutritionists, food scientists, and nurses), and State government officials and agencies.

Most of the comments from individual consumers focused on the requirements for finished meat food product labeling and the commenters' interest in using or avoiding product made by the mechanical separation and removal process. Most of the comments from industry, on the other hand, addressed the more technical aspects of the proposal, including various aspects of the definition and standard for this product (e.g., compositional and quality control requirements) and limitations on its use, as well as finished product labeling requirements and the benefits the product can provide.

The Department also received approximately 60 comments that were postmarked after October 29, 1981. Most of these comments were submitted by individual consumers; the remainder came from industry members, a trade association, professionals, and a State government agency. The Department has reviewed these comments. While they are not specifically referred to in

the discussion of the final rule, the views they contain also were expressed by other commenters whose submissions are summarized in that discussion.

After reviewing the comments submitted by the public in light of currently available information, and in view of the importance of taking advantage of all safe and wholesome sources of food, the Department determined that certain of the regulations which it promulgated in 1978 should be amended in order to facilitate the production and use of this product while continuing to protect the public against the preparation and distribution of adulterated and misbranded products.

The Final Rule

The final rule amends the Federal meat inspection regulations by modifying the definition and standard (including parameters for measuring compliance) and permitted uses for the product defined by regulation in 1978 as "Mechanically Processed (Species) Product" ("MS(S)P") and the labeling requirements for meat food products in which it is used as an ingredient, and by establishing labeling requirements for such product. The amendments contain the following provisions:

1. The definition and standard for the product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts is amended to include a new product name and two categories of product and to clarify its scope (9 CFR 319.5).

(a) The definition and standard is amended to clarify its scope by specifying that it applies to "finely comminuted" product.

(b) The name of the product is changed to "Mechanically Separated (Species)" in order to provide a more meaningful and concise description of its characteristics.

(c) The maximum bone particle size and bone solids content requirements are retained, but the definition and standard are amended to clarify that the maximum calcium content is a measure of maximum bone solids content and that product failing to meet the maximum bone particle size requirement shall be used only in producing animal fats.

(d) The definition and standard is amended to include two categories of product; one which meets maximum fat and minimum protein content requirements (not more than 30 percent fat and not less than 14 percent protein), and a second as to which there are no

fat or protein content requirements (product for processing).

(e) The minimum protein quality requirement (a PER of 2.5) is retained, but the definition and standard is amended (1) to permit use of product failing to meet the protein quality requirement only in producing animal fats, (2) to clarify the compliance provision by specifying the amino acids included in a calculation of total amino acids and simplify the provision by focusing on the comparison that is to be made between essential amino acid content and total amino acid content, and (3) to control the costs of measuring compliance by deleting cystine from the calculation of total amino acids.

(f) An approved plant quality control system for establishments producing the product is retained as a prerequisite for label approval for products consisting of or containing the product, but the requirements are modified as follows: (1) USDA's 1980 regulations regarding applications for plant quality control, their evaluation and approval by the Administrator of FSIS, and the conditions and procedures for terminating approval (9 CFR 318.4(d) (1) and (2), (e), and (g)(2)) are incorporated, (2) provisions designed to assure compliance with fat and protein content requirements are restricted to product which purports to meet such requirements, (3) the use of Chemistry Laboratory Guidebook methods is permitted if no AOAC method is available and provision is made for the submission of alternative methods of analysis to the Administrator of FSIS to determine their acceptability, (4) the quantity of product which may constitute a "lot" is clarified, and (5) the acceptability of methods other than laboratory analyses for assuring compliance with the bone particle size requirement and of either PER assays or amino acid content analyses for assuring compliance with the protein quality requirement is clarified.

2. The requirements for the handling of material for mechanical processing and the handling of the product itself are retained, but the references to "MP(S)P" and an imitation of "MP(S)P" are replaced by "MS(S)" (9 CFR 318.18).

3. Limitations on use of the product are retained to prevent potential health and safety problems and protect the quality and integrity of the meat food product supply, but the restrictions are modified to take into account the establishment of two categories of product; the scope of the restrictions is clarified; and the cross reference to labeling requirements (9 CFR 317.2(j)(13)) is eliminated as redundant (9 CFR 319.6).

(a) Product meeting fat and protein content requirements can be used in any meat food product in which its use is not prohibited; and product for processing can be used only in such a meat food product that is subject to a regulatory definition and standard which limits fat content.

(b) The list of meat food products in which use of the product is prohibited is clarified.

(c) The restriction on the amount of product that may be used in any meat food product is retained, but the basis for determining that limit is clarified as including all livestock and poultry product ingredients.

4. The definitions and standards of identity or composition for meat food products (9 CFR Part 319) in which the product may be used are amended as follows:

(a) "Mechanically Processed (Species) Product" is replaced by "Mechanically Separated (Species)".

(b) Those definitions and standards which limit fat content by setting a maximum on the amount of trimmable fat that the ingredients used in their formulation may contain (9 CFR 319.141, 319.143, 319.144, and 319.160) are amended to define the limit in terms of a maximum analytical content (50 percent) in order that product for processing may be used in their formulation.

(c) Certain of those definitions and standards (9 CFR 319.140, 319.145(a)(3), 319.281, and 319.305) are amended to clarify that use of the product is permitted.

5. A labeling requirement is established for the product to ensure that it is used in accordance with regulatory requirements; and the labeling requirements for meat food products in which it is used are amended to continue to provide adequate, nonmisleading information while reducing their burden and avoiding unwarranted and possibly derogatory implications (9 CFR 317.2(j)(13)).

(a) On the label of the product itself, the name of the product must be followed immediately by the phrase "for processing" unless such product contains not more than 30 percent fat and not less than 14 percent protein.

(b) The requirement that the name of the product must be listed in proper order of predominance in the ingredient statements of meat food products in which it is used, consistent with the general requirements for declaring ingredients in meat food products (9 CFR 317.2(c) (1) and (2) and (f)(1)), is retained, but the repetition of this

requirement (in 9 CFR 317.2(j)(13)) is deleted as redundant.

(c) The requirement that the names of meat food products must be qualified to indicate the presence of this product as an ingredient is deleted as unnecessary where such ingredient can constitute only 20 percent or less of the livestock and poultry product portion.

(d) The requirement that the names of meat food products must be further qualified to indicate the amount of powdered bone they contain is replaced with a requirement that their labels declare calcium content as part of nutrition labeling information—or if the meat food product does not bear nutrition labeling, in a prominent statement in immediate conjunction with the ingredients list—where the product contributes 20 mg or more of calcium to a serving, unless the amount that would be declared would not differ from the amount that would be declared if the meat food product contained only hand deboned ingredients or unless the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more if the meat food product contained only hand deboned ingredients.

The final rule is discussed below. The organization of that discussion follows the outline set out in this summary.

Discussion of the Final Rule

1. Product Definition and Standard

(a) Scope of the definition and standard.

The product definition by the name "Mechanically Processed (Species) Product" in 1978 is made by mechanically separating and removing most of the bone from attached skeletal muscle of livestock. While it is possible to use whole carcasses, the raw materials for this type of processing generally are parts of carcasses from which most of the skeletal muscle already has been removed by traditional hand deboning techniques. With the mechanical deboning technology, these bones generally are broken up and pushed under high pressure through equipment with apertures that allow a small amount of powdered bone to pass through with the soft tissue. The resulting product differs from the hand deboned product, traditionally used as an ingredient, due to its highly comminuted and spread-like consistency and its content of varying amounts of bone, including bone marrow, and certain minerals as well as muscle tissue.

Several commenters referred to the variety of deboners currently available

for commercial use as well as the characteristics of product made by these machines. One commenter also noted procedures currently in the developmental stage, including liquid separation techniques. Another commenter expressed concern that the present definition could be broad enough to extend to products which it was never intended to cover, as technology increasingly enables industry to remove bones from primal cuts by mechanical means rather than by hand, and recommended that the scope of the regulations be limited to the product intended to be covered.

The Department is aware that technological advances are occurring in the meat processing industry and it wishes to avoid confusion about the scope of the definition and standard in § 319.5 of the regulations (9 CFR 319.5). This regulation does not specify the type of equipment used to separate and remove bone because it is intended to cover the product manufactured by any such machinery that operates on the differing resistance of hard bone and soft tissue to passage through small openings, whether it employs sieves, screens, or other devices and whether or not bones are prebroken before being fed into such equipment. However, the regulation is not intended to apply to whole pieces of muscle which have been removed from livestock bones by mechanical or other means. In view of concern expressed about possible misapplication of this definition and standard to products which it is not intended to cover, the Department is amending the regulation to clarify its scope by inserting the words "finely comminuted" in the description of the product, which now will specify that it extends to:

*** Any finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses and meeting the other provisions of (9 CFR 319.5(a)).

As the modified language does not change the current scope of the regulation, it is being adopted as part of this final rule.

Several industry commenters challenged the appropriateness of retaining a separate definition and standard for this product, arguing that its characteristics clearly place it within the regulatory definition of "meat." As the Department noted in its proposal, the consistency of this product and its content of bone, including bone marrow, and certain minerals as well as muscle tissue are materially different from those of meat; and these differences

have potential consequences for finished product quality and for health and safety. Thus, while the product has many of the characteristics of "meat" and, if properly regulated, can be used as a "meat" ingredient in the formulation of quality meat food products, it is sufficiently different that it cannot be regarded as falling within the category of food traditionally defined as "meat" (9 CFR 301.2(t)). The product should be separately defined and standardized, and identified by a name that adequately differentiates it from "meat". 46 FR 39274, 39275, 39283. See also *CNI v. Butz*, supra; 43 FR 26416, 26420. The comments on the proposal contained no new information to refute this position. In fact, numerous comments attested to the distinctive nature of this product. These comments are summarized in the following sections of this discussion.

(b) Product name.

The Department proposed to amend the definition and standard (9 CFR 319.5(a)) by deleting the term "product" from the product name and by considering terminology such as "mechanically separated", "mechanically deboned", and "mechanically recovered" as an alternative to "mechanically processed" to distinguish the product from "meat". 46 FR 39274, 39283-84. The Department has concluded that "Mechanically Separated (Species)" ("MS(S)") should be adopted as the product name in the amended regulations because this name will provide a more meaningful and concise description of the product's characteristics than "Mechanically Processed (Species) product".

Three hundred and sixty-one comments addressed issues bearing on the name of this product. They were submitted by the full spectrum of individuals and groups commenting on the proposal, with the majority coming from individual consumers and about 25 percent from industry-related individuals and groups. Most of these commenters supported some modification of the name "Mechanically Processed (Species) Product", although a number of the comments from individual consumers expressed general opposition to changing the product name.

Many of the commenters supported the Department's proposal to delete the term "product". Some of these commenters said this should be done because the term "product" is not essential to assuring that the name accurately identifies the product and/or it is confusing.

On the other hand, a few commenters objected to this proposed change in the current product name, taking the

position that the term "product" is necessary to convey that this ingredient is different from meat. One of these commenters questioned the basis for the Department's policy reversal from its 1978 conclusion that use of the term "meat" would incorrectly represent that the product consists solely of meat. Relying on Market Research Services' focus group research for this purpose was criticized because the observations of focus group research are limited to the participants and are not statistically valid or representative of the population at large; and as neither tape recordings nor transcripts of the sessions were made available and the verbatim responses to one question are restricted to the sessions in 3 of the 4 cities, one cannot be assured that there was no distortion or manipulation of consumer responses or verify Market Research Services' conclusions. Nevertheless, this commenter asserted that what was provided in Market Research Services' report contradicts the Department's position and demonstrates the necessity of the term "product" to prevent consumer deception.

The Department's proposed departure from its earlier policy on the need for the term "product" was based primarily on its belief that in 1978 the Administrator had failed to consider the name as a whole—as opposed to the single word "meat"—and that the requirement imposed then is inconsistent with the Department's policies and requirements regarding the names of other livestock products. In addition, from a review of Market Research Services' report, it appeared to the Department that inclusion of this term might confuse or mislead consumers and that the source of the problem might be the very inconsistency of requiring "product" in the name of this livestock product, but not others. 46 FR 39274, 39283. In citing this research report, the Department recognized that focus group research does not provide results which are projectable to a larger population and, thus, the findings of such research must be regarded as tentative or indicative of potential trends or attitudes. The Department also recognized that it had not yet completed its evaluation of the report and the conclusions drawn therein by reviewing tapes or transcripts or the sessions. 46 FR 39274, 39281. After completing this evaluation, the Department continues to be concerned that the inclusion of the term "product" in the name may result in inaccurate perceptions about the source and nature of the product. For example, Market Research Services reported that a number of the

participants perceived the term "product" as modifying the species identification (e.g., "beef") to indicate that inferior animal parts such as lips, ears, and hooves have been used in making the product, that it either contains substantial ingredients in addition to meat or does not contain meat at all, or even that it contains artificial ingredients or is fabricated from non-livestock or non-food ingredients.

Most of the commenters addressing the question of product name indicated a preference, or a first and second preference, as to what the product should be called; and a number of them also indicated why they believed other names to be inappropriate. Each of the four options set forth in the proposal—"mechanically processed", "mechanically separated", "mechanically deboned", and "mechanically recovered"—received at least some support in the comments. However, "Mechanically Recovered (Species)" ("MR(S)") was supported only by one commenter and only as a second choice that would be better than "mechanically processed" or "mechanically deboned". Other commenters who addressed this option rejected it, with some saying that, as compared with other options, it would lend itself to potential confusion, would be less understandable or misleading, is not really descriptive, and/or potentially covers a number of functions with no indication from where or what the product is recovered. Moreover, one of the comments stated that under proposed United Kingdom regulations, the product would be regarded as "meat". Thus, the one place in which this terminology has been used appears to be abandoning it.

The other three alternatives each received greater support than MR(S), but each also was the subject of criticism. "Mechanically Deboned Meat" or, as set forth in the proposal, "Mechanically Deboned (Species)" ("MD(S)") was the alternative name most favored in the comments. Many of the industry commenters supporting this alternative based their position on the extensive use of this terminology by industry (domestically and/or internationally) to describe the meat and poultry products manufactured by this technology, with some asserting that such usage has resulted in common or usual name status which should be recognized by USDA. Some stated that this name is self-explanatory, the simplest, more or the most accurate or descriptive, least misleading, and/or that it would be more understandable to consumers or

less likely to be confusing or controversial than other alternatives; and Market Research Services' work was cited as supporting this position.

Criticism of MD(S) focused on the issue that concerned the Department in its prior rulemaking and its current proposal: that the term "deboned" would incorrectly represent to consumers that the product does not contain bone, including bone marrow. 43 FR 26416, 26420; 46 FR 39274, 39284. One commenter cited Market Research Services' report of focus group participants' reactions as confirming the Department's 1978 conclusion and contended that it is likely "mechanically deboned" evoked more positive responses from the participants because it gives an incorrect and euphemistic image.

A number of commenters supported "Mechanically Separated Meat" or, as set forth in the proposal, "Mechanically Separated (Species)" ("MS(S)") as a first or second choice on the ground that it is more descriptive of the product than other alternatives; and one said that if consumers are aware that one component is meat, most will know meat is being separated from bone. This name also was favored because of its use in several other countries and its adoption by the 10th session of the Codex Alimentarius Committee on Processed Meat and Poultry Products (1978). "Mechanically Processed (Species)" ("MP(S)") was supported by some commenters as being truthful and understandable. MP(S) and MS(S) also were preferred as not having the negative connotations associated with "mechanically deboned" or "mechanically recovered", although a few commenters asserted that because of the controversy surrounding the name MP(S), MD(S) should be adopted rather than MP(S).

Criticism of MP(S) and MS(S) came from commenters supporting MD(S) who took the position that "mechanically processed" and "mechanically separated" are less descriptive, having no obvious connection to the separation of meat from bone, or potentially confusing. MP(S) also was criticized as negative and as uninformative or misleading because, for example, most foods are processed at least to some degree and because "processed" has traditionally been used to describe cooked or cured products. MS(S) also criticized as not making clear what is being separated from what.

In addition to addressing the four options set out in the proposal, the comments include some support for alternative terminology. One commenter

suggested "mechanically extracted" as a means to alert consumers to a new and different process. Another recommended "mechanically trimmed" as descriptive of the product and not having the negative or misleading connotations of "deboned" or "processed". Two commenters suggested "mechanically boned" as more descriptive and less burdensome than the options in the proposal. Two others favored using just the term "deboned" because, according to one of them, this is most descriptive and, according to the other, the term "mechanically" serves no useful purpose and is misleading. Finally, one commenter recommended that the name of the product be "Tissue from Ground Bone" ("TFGB") in order to provide a clearer, and thus more meaningful, description of the product.

The Department has determined that it should not adopt any of the alternatives that incorporate the word "deboned" or "boned" because such names might mislead consumers. In its proposal, the Department cited its 1978 determination on this issue and expressed its continuing concern that the phrase "mechanically deboned" would erroneously represent that the product differs from meat solely in the manner by which bone has been removed. 46 FR 39274, 39284. Nothing submitted during the comment period has allayed this concern. In fact, its legitimacy has been emphasized by the many commenters who said this product is simply meat that has been separated from the bone by mechanical means. As was noted by a number of commenters, this is not the case: the product also contains bone, including bone marrow.

The Department also still ascribes to its 1978 determination that the name "TFGB" could be misleading as this product contains both meat and bone, including bone marrow, and "TFGB" would incorrectly indicate that it is made wholly from parts of bone. 43 FR 26416, 26420. In addition, the Department has concluded that the name of this product should continue to include the term "mechanically" to indicate the nature of the process used in making the product.

The Department has determined that the name "Mechanically Processed (Species) Product" should be replaced by "Mechanically Separated (Species)" in order to provide a concise and accurate description of the product without confusing or misleading consumers. Based on the factors discussed in the proposal and the comments on this subject, the Department believes that the alternative

it has selected is most likely to achieve this goal. The adoption of this name reflects the Department's conclusion that, as with other livestock-derived ingredients (e.g., "variety meats", "partially defatted pork fatty tissue"), the term "product" is not an essential element of a nonmisleading product name and that its use in this, but not other, product names may result in consumer misperceptions. The adoption of this name also reflects the Department's conclusion that because "mechanically separated" is more specific than "mechanically processed", the new name should be more meaningful to consumers. For example, Market Research Services' report indicates that "mechanically processed" may be confusing to consumers when used on the label of a frankfurter because they believe all such products are processed. Moreover, adoption of this name will make USDA's regulations consistent with those proposed in Canada and with the ongoing work of the Codex Alimentarius Commission and other countries, an advantage not presented by the other options considered.

Finally, the Department recognizes that the ability of any name to communicate in only a few words the nature of a new product is limited. In this regard, a few commenters expressed support for an effort to provide consumers with information about this product. One urged the Department to educate consumers about the product's composition and uses. Another said that the safety aspects of consuming the product need to be addressed. Others were of the view that such an effort would be in the best interest of industry as well as consumers by correcting misconceptions about the product (e.g., that it is responsible for tooth damage).

The Department believes that it is important to inform the public about this new product. Therefore, it will be reviewing its public information program and revising it to incorporate explanatory material on the process used to make MS(S) and the product's characteristics. The Department also believes that industry has a role to play in this effort, and will work with industry members and associations interested in designing their own informational materials. Similarly, the Department is interested in working with other groups which choose to develop information for consumers.

The Department also received a number of comments that went beyond the issues set forth in the proposal. Some of these comments challenged the

underlying premise of having any distinctive name for the product, asserting that it is skeletal meat and, as such, the only appropriate name is that of the species from which it was produced (e.g., "beef", "pork"). As has been noted above, MS(S) does not consist solely of skeletal meat and its composition and consistency differ materially from the product defined by regulation as "meat" (9 CFR 301.2(tt)). Therefore, it should be known by its own distinctive name.

Other industry commenters accepted the appropriateness of a distinctive product name, but raised questions about its application to their products. These concerns focused on the scope of the term "species" as used in the product name. The illustrative examples set forth in the proposal to modify the definition and standard (9 CFR 319.5(a)) include "beef", "veal", and "pork". The Department intended this generic description to include product made by applying the mechanical deboning technology to any livestock covered by the FMIA, 21 U.S.C. 601; see also 9 CFR 301.2(rr), (ss), and (ww). Therefore, "species" includes beef, veal, calf, pork, mutton, lamb, goat or chevan, horse, and equine products. In response to concerns expressed by members of the sheep industry, the Department is clarifying this by adding "Mechanically Separated Lamb" to the list of examples in the regulation.

Also, several pork product producers commented that the name should identify product made from certain primal parts such as the ham. One commenter said this should be done because listing "mechanically deboned pork" in the ingredient statements of meat food products such as chopped ham would confuse consumers. The Department did not intend the term "species" to include primal parts of livestock species, nor does it believe that such an expanded use of this term would be appropriate. Primal parts are the distinct wholesale cuts of a carcass that are customarily distributed to retailers (e.g., the round, flank, and brisket for beef and the ham, belly, and shoulder for pork) (see 9 CFR 316.9). Such cuts consist primarily of whole pieces of muscle meat. Bone is included only to the extent that it accompanies such cuts and has not been removed in the dressing process. Thus, it is muscle meat and not any accompanying bone that characterizes primal parts; and, in the Department's view, product made from any accompanying bones does not retain the distinctive characteristics of the cuts themselves.

However, these comments raised issues that concern the Department: the appropriateness of continuing to permit use of this product in meat food products, such as pressed ham, chopped ham, and deviled ham (9 CFR 319.104(f), 319.105, and 319.760), that are represented as having been made from a particular part of the carcass and, if such use continues to be permitted, whether consumers might be confused by ingredient statement declarations of "mechanically separated pork" in such products. Therefore, as discussed below, the Department plans to reconsider certain of its limitations on the use of MS(S). In addition, if the manufacturers of such products can substantiate that the mechanically separated product they are using was made solely from bones which accompany ham meat, the Department would consider permitting finished product labeling to reflect that fact in the following manner: "mechanically separated pork (made from ham bones)".

(c) Bone particle size and bone solids content

The Department did not propose changing the maximum bone particle size or bone solids content limits established in 1978 (9 CFR 319.5(a)). However, it did propose to clarify these requirements by explicitly recognizing that (1) a maximum calcium content of 0.75 percent is used as a measure of a bone solids content of not more than 3 percent and (2) product failing to meet the maximum bone particle size requirement—at least 98 percent of bone particles not exceeding 0.5 millimeter (mm) and no bone particle larger than 0.85 mm—can be used only in producing animal fats. 46 FR 39274, 39284. The Department has decided to adopt these clarifying amendments.

Additionally, in view of the Canadian government's proposal to permit larger bone particles—98 percent less than 0.84 mm and 100 percent less than 2.0 mm, the Department indicated it was open to new information that good manufacturing practice may result in somewhat larger bone particles than currently are permitted; and it requested persons commenting on this issue to submit data on the safety and digestibility of bone particles larger than those now permitted. 46 FR 39274, 39284. As adequate information on which to base a modified requirement was not submitted, the Department is retaining the existing limit. However, it continues to be willing to reexamine this limit on the basis of such information and data.

Bone Particle Size

Sixty-five comments addressed bone particle size issues. Almost all of these comments were submitted by industry-related individuals and groups. Most of those commenting on the bone particle size limit were more concerned with the compliance aspect of this requirement than with the limit itself. Those comments are addressed below in connection with the Department's quality control requirements.

Many of these commenters favored increasing the current bone particle size limit, particularly in light of the Canadian government's proposal to permit somewhat larger bone particles. It was contended that the Canadian proposal reflects the capability of deboning equipment and current good manufacturing practices and that it is premised on a much larger data base than was available when the Department promulgated its requirement, but no information was provided to support this position. It also was contended that bone particles of the sizes set forth in the Canadian proposal pose no health or safety problem, but no supporting information was submitted. Other commenters stated that product made by mechanically deboning poultry carcasses contain larger bone particles and there have not been health or safety problems with that product. Finally, several commenters suggested deleting this requirement entirely, indicating that industry should self-regulate in this area, and one suggested basing the requirement on the species and parts of the carcass used to make the product because bone particle size varies by species and part.

The commenters supporting retention of the existing limit, on the other hand, felt that it is attainable with various types of available equipment and that it is unwise to jeopardize product quality and consumer acceptance merely to accommodate the state of the art in certain types of deboning equipment. Some of those taking this position also indicated that if the limit were increased, bone particles could be detected and a gritty texture and/or dental problems might result.

Despite the assertions of a number of commenters favoring an increase in the bone particle size limit, the Department has determined that such a change should not be made on the basis of the information it now possesses. The Department imposed this regulatory restriction in response to a recommendation of the Panel convened to evaluate health and safety aspects of the use of product made by mechanically deboning livestock

carcasses. After considering detailed information on the bone particles produced by a number of different machines from a variety of livestock bones, the Panel concluded that the size of such particles presents no hazard to health and recommended that regulatory maximum be imposed to, in the words of the subcommittee that addressed this question, "limit particle size to those levels presently [i.e., in 1977] associated with good manufacturing practice." "Those levels" were well within the current regulatory maximum. Since that time, the Department has not received any additional information substantiating the absence of safety or digestibility problems with larger bone particle sizes.

Contrary to assertions by several commenters, data reviewed in 1979 regarding the product made by mechanically deboning poultry carcasses with auger-type equipment indicate the bone particles in that product also fall within the existing regulatory limit for product made by mechanically deboning livestock carcasses. However, the Department notes that some commenters reported finding pieces of bone in various poultry products. In any event, determinations about the size of bone particles associated with good manufacturing practice in the production of one of these products are not necessarily applicable to the other; nor are determinations about the safety and digestibility of their bone particles.

The Department also is concerned by comments that product with bone particles in excess of 0.85 mm would be detectable and, thus, adversely affect the quality of products in which MS(S) is used as an ingredient. As the Department noted in its first proposal to regulate this product, if bone were present in such a particle size (or amount) as to be readily apparent to the taste or touch, it would be identifiable as bone and be a reason to consider the product adulterated. 41 FR 17560, 17561. Moreover, the Department has not seen any data refuting its earlier conclusion that the existing limit is readily attainable with available equipment operated in accordance with good manufacturing practice.

As the Department indicated in its proposal, it does not wish to discourage the development of additional types of mechanical deboning equipment and processing procedures, particularly those capable of separating out and removing more bone. 46 FR 39274, 39284, 39288. Such technological developments may well generate data substantiating the absence of problems with somewhat

larger bone particles; and the Department remains open to a reconsideration of this aspect of the regulations on the basis of such information.

Bone Solids Content

The 7 comments addressing the Department's retention of a 0.75 percent maximum on calcium content were submitted by industry-related individuals and groups and a university faculty group. These commenters generally accepted the appropriateness of this limit, with some supporting it as consistent with the operation of various types of equipment currently in use in accordance with good manufacturing practice. Only one commenter suggested a different level—1.0 percent—and he gave no reason why the current maximum should be raised. The Department does not know what prompted this suggestion since the data reviewed by the Panel indicate that deboning equipment generally yields a product with a calcium content well below the 0.75 percent maximum and in view of other comments regarding the ability of newer equipment to yield a product with an even lower calcium content.

(d) Fat and protein content

The Department proposed amending the definition and standard (9 CFR 319.5(a)) to include two categories of product: (1) A category which meets the existing fat and protein content requirements for MP(S)P—not more than 30 percent fat and not less than 14 percent protein—and (2) a category "for processing" as to which there are no fat or protein content requirements. 46 FR 39274, 39284–86. The Department has determined that this portion of the proposal should be adopted. This determination rests on its conclusion that when applied to all uses of the product, these fat and protein content requirements are unnecessarily restrictive; but when limited to certain uses, they are a necessary and appropriate method for preserving the quality and integrity of the meat food product supply.

The absence of any significant production of mechanically separated product under the 1978 regulations, the analysis of potential supplies for mechanical deboning by Drs. Bullock and Ward and the Department, and the comments on the proposal have convinced the Department that, in order to expand food supplies significantly by taking advantage of the full range of materials available for mechanical deboning, a second category of product without fat and protein content

requirements should be established. The Department also has concluded that this can be done while continuing to prevent increases in meat food products' fat content and assuring that the public can continue to rely on such products as reasonably good sources of high quality dietary protein. This amendment will permit greater flexibility in product composition to the extent that the compositional requirements for finished meat food products established by various definitions and standards of identity and composition (9 CFR Part 319) and the requirement that MS(S) be produced under a quality control system which maintains adherence to good manufacturing practice (9 CFR 319.5(e)(2)) can be relied upon to assure that the resulting variability does not compromise the integrity of finished meat food products.

One hundred and seven comments addressed this aspect of the Department's proposal. The majority of these comments were submitted by industry-related individuals and groups. A number of individual consumers also commented on this aspect of the proposal, as did several State government officials and agencies and a public interest organization. Most of these commenters objected to the imposition of fat and protein content requirements for any category of the product. However, a number of them said they oppose such requirements either because fat or fat and protein content already is controlled in all finished meat food products in which mechanically separated product may be used as an ingredient or because the proposal would impose such requirements on mechanically separated product used in finished products the fat content of which already is limited by regulation. Neither of these assertions is correct: First, as the Department noted in its proposal, a large proportion of the meat food products consumed in this country, and in which MS(S) may be used as an ingredient, is not subject to regulatory definitions and standards. Even where standards do exist, they do not impose direct limits on finished products' protein content and frequently do not limit their fat content. 46 FR 39274, 39287. Second, the precise objective of the Department in proposing to establish two categories of product was to restrict fat and protein content requirements to MS(S) used as an ingredient in meat food products the total fat content of which is *not* already limited by regulation.

Other commenters specifically opposed the establishment of two categories of product, recommending

instead that there continue to be only one category and that it not be subject to any fat or protein content requirements. The basic reasons given for this position were that such requirements are not needed, without precedent, discriminatory, and/or they will not be effective. In addition to these comments questioning the logic and legitimacy of such requirements, the Department received comments asserting that the imposition of any fat and protein content requirements will preclude the deboning of some portions of swine and cattle carcasses or the use of product made from some types of livestock carcasses in at least some meat food products. Some of these commenters did acknowledge that by not imposing fat and protein content requirements on product for processing, the proposal should enable greatly increased production of MS(S); and it should be noted that some did not appear to understand the extent to which the proposed regulations would permit use of MS(S) regardless of its fat or protein content. The proposed approach also was criticized as making the manufacture of MS(S) complex because fat and protein content would have to be monitored.

A number of commenters challenged the retention of compositional requirements for any product made by the mechanical separation and removal process on the ground that such requirements cannot control the fat content of finished meat food products. These commenters' basic point was that because the fat content of only this one ingredient would be limited, it could be combined with fatty hand trimmed ingredients into finished products with a higher fat content. Several commenters asserted these requirements also are inequitable because hand trimmed ingredients and product made by mechanically deboning poultry carcasses are not subject to such limitations and/or they are not needed because this product will have the same composition as the meat it replaces. Some commenters contended that historically the composition of nonstandardized products has been limited by competition and consumer taste, and this approach should be followed here; some concluded that if fat and/or protein content requirements are necessary, they should be applied to finished products, not intermediate ingredients; and one proposed that if two product categories are established, the "better" one (i.e., product meeting fat and protein content requirements) be considered as meat and the other (i.e., product for processing) as a meat

byproduct. Finally, it was argued that the concept of "good manufacturing practice" suggested by the Panel as the basis for limiting the fat content of this product should include the conservation by mechanical deboning of product with the same general characteristics as that recovered by hand deboning; and, to the extent the Panel's recommendation was to limit the fat in this product in order to counterbalance other, unlimited sources of fats and oils in the food supply, it was outside the scope of its charge to evaluate the health and safety of mechanically separate product.

The Department must admit that it did not anticipate certain of the challenges by industry to the legitimacy of fat and protein content requirements. While the Department agrees that marketplace forces and consumer preferences and satisfaction are important factors in determining product acceptability and success, it has long been acknowledged that they are not always adequate to control product composition within appropriate parameters. For example, the development 30 years ago of equipment and technology that made it possible to hold large quantities of fat in suspension during cooking and smoking meant that the incorporation of excessive amounts of fat in cooked sausages such as hotdogs—and the resultant, undetectable diminution of protein content—would no longer make such products unmarketable. Therefore, the Department established a regulatory limit on the fat content of these products (see 9 CFR 319.180). The adoption of other technological advances also has diminished consumers' ability to evaluate the characteristics and quality of various products. As a result, the Department has found it necessary to institute compositional and labeling requirements to prevent adulteration and misbranding.

Although such requirements most frequently have been applied to finished products, the establishment of compositional limits for ingredients certainly is not unprecedented. The most obvious example of an ingredient level requirement is the one discussed in the Department's proposal: the maximum on the amount of trimmable fat that may be present in any lot of product used to make various meat food products. 46 FR 39274, 39290. The Department is replacing this limit with a limit on finished product fat content in four of its standards (9 CFR 319.141, 319.143, 319.144, and 319.160) only in order that MS(S) for processing may be used in the formulation of products they cover (fresh pork sausage, breakfast sausage, whole hog sausage, and smoked pork

sausage). Thus, the same type of requirement will continue to be employed where use of MS(S) is not permitted (see 9 CFR 319.313, the standard for beef with gravy and gravy with beef). As one commenter noted, visible lean, as opposed to trimmable fat, also is considered by the Department in determining the acceptability of hand trimmings for use as ingredients in meat food products; and such determinations take into account whether or not the total fat content of such meat food products is limited by regulation, the same criterion used in these amended regulations. As the Department noted in proposing to amend four of the standards utilizing a limit on the trimmable fat of ingredients, that type of control requires a visual evaluation of solid pieces of meat; hence, it cannot be applied to the highly comminuted product produced by mechanical deboning. 46 FR 39274, 39290. Therefore, an analytical limit is more appropriate for this product.

Similarly, while it is true that there are not compositional requirements specifically applicable to product made by mechanically deboning poultry carcasses, that product is subject to the general requirements in the poultry product regulations (9 CFR Part 381). Those regulations differentiate between "poultry meat" and "poultry", with the former term restricted to product without skin or fat (i.e., fatty tissue attached to the skin) and the latter term also encompassing other edible parts, such as skin and fat not in excess of their natural proportions. As skin and fatty tissue are the places in which most of the fat in chickens and turkeys are found, these definitions serve to limit fat content indirectly and to distinguish between classes of poultry products in terms of their relative fat and protein contents. Moreover, they have consequences for product use since many of the standards for finished poultry products include minimum poultry meat requirements. At this time the Department has made no decisions with respect to additional regulatory action regarding product made by mechanically deboning poultry carcasses or as to the appropriateness of regulating that product in the manner that these revised regulations will regulate MS(S). However, it cannot be said that there currently are no constraints on the composition of that product.

In addition to limits on the composition of ingredients, the Department protects the public by regulating the type of ingredients that various meat food products may contain

and, where appropriate, assuring that the proportions of ingredients they contain are sufficient to provide the characteristics they are represented as having. See sections 1(m)(8), 1(n) (2), (7), and (9), and 7(c) of the Federal Meat Inspection Act (21 U.S.C. 601(m)(8) and (n) (2), (7), and (9), 607(c)). The focus of interest in such inquiries frequently is the quality and quantity of livestock product components. Thus, in regulating MS(S), the Department's concern is that its use in lieu of other livestock products will be consistent with the characteristics consumers associate with and expect of various meat food products and will not result in a diminution of such products' quality. MS(S) consists largely of muscle tissue, rather than parts of the carcass such as the spleen, liver, and tripe that have traditionally been restricted to use as byproducts. Therefore, the Department has agreed that manufacturers should be able to use this product as a meat ingredient in their processing formulations so long as finished product integrity is protected and that the names of finished products need not always be qualified to indicate its presence. However, this position rests on MS(S) not deviating significantly from certain of the characteristics associated with meat. Hence, the amended regulations retain a protein quality requirement; and they retain fat and protein content requirements to the extent to which other controls have not been shown to provide adequate protection against a lowering of the quality (including the nutritional quality) and expected characteristics of the meat food product supply.

The Department thus continues to ascribe to the position it took when, in 1976, the regulation of product made by mechanically deboning livestock carcasses and parts first was considered: While the Department wishes to facilitate efforts to expand the food supply through advances in technology, its actions must be consistent with its statutory responsibilities. Therefore, any reconsideration of the regulatory requirements must take into account the differences between this product and both meat that is processed only to the extent of cutting or grinding (e.g., steaks and hamburger) and the manufacturing meats traditionally used in formulating processed meat food products. With the technological advances that permit the manufacture of products from portions of carcasses previously not considered part of the meat food product supply comes a greater potential for a diminution of quality and the

characteristics associated with the meat food product supply. Although the Department has considered a number of different regulatory provisions to prevent such problems, its basic objectives and approach have remained the same. As the Department stated in its 1976 proposal, it is necessary to establish standards which assure the consumer that the inclusion of new products like MS(S) in formulated meat food products will not dilute the nutritional quality normally and traditionally associated with such products. 41 FR 17560, 17560-61. By maintaining the quality and expected characteristics of such products, these regulatory requirements prevent an erosion of public confidence in the meat food product supply and, hence, protect the agricultural community by preventing damage to the markets for their products, in accordance with the goals of the FMIA. 21 U.S.C. 601, 602.

The judgments about the appropriateness of specific regulatory provisions that are reflected in these amended regulations are based on the information currently available to the Department. The amended regulations incorporate the Department's conclusion that where other regulatory controls provide adequate protection against reductions in product quality, fat and protein content requirements serve primarily to limit the use of MS(S), but not hand trimmings, in the mixtures of livestock ingredients that generally are blended together in the manufacturing process. Therefore, the Department is amending the regulations to provide manufacturers with greater flexibility to incorporate MS(S) in these mixtures and, thus, take greater advantage of market fluctuations to produce economical products.

Moreover, from the information currently available, the Department does not agree with those commenters who asserted that the proposed two product category approach will prevent utilization of the full range of materials available for mechanical deboning. These comments presented no data to demonstrate that the establishment of a category of product for processing would not provide adequate outlets for mechanically separated product, regardless of its fat or protein content; and they disregard the extent to which processors can control the composition of mechanically separated product by techniques such as varying the degree of pretrimming performed before mechanical deboning.

In fact, the available data indicate that the amended regulations would not preclude the deboning of some parts or

types of livestock. For example, Drs. Bullock and Ward estimated the economically feasible 1979 level of beef and pork product production at 351.7 million pounds if, as they recommended, the names of finished meat food products did not have to be qualified and the fat and protein content of product made by mechanical deboning were not restricted. The economically feasible 1979 level without these labeling requirements but with the 30 percent fat content maximum and 14 percent protein content minimum was estimated to be 87.2 million pounds. 46 FR 39274, 39348-49. Thus, according to these analysts, 264.5 million pounds of the potential supply of this product would not have met one or both of these compositional requirements. The Department estimates that approximately 3.1 billion pounds of standardized cooked sausages such as hotdogs and bologna (9 CFR 319.180)—products in which fat content is limited and use of MS(S) is particularly likely—were produced in federally inspected plants in 1979. The livestock (or livestock and poultry) product portion constitutes about 85 percent of these meat food products, or 2.6 billion pounds in 1979. Thus, the estimate by Drs. Bullock and Ward of the potential supply of the product that the amended regulations categorize as product for processing is just over 10 percent of the livestock product portion of these cooked sausages, or only about half of the maximum amount permitted. Product for processing also is permitted in a number of other popular meat food products such as fresh pork sausage (9 CFR 319.141) and fresh beef sausage (9 CFR 319.142), with production of these two products totalling approximately 0.84 billion pounds in federally inspected plants in 1979. In addition to these uses, potential outlets for product for processing, as well as product meeting fat and protein content limits, exist in the export market. Finally, the Department is willing to consider expanding existing outlets for product for processing by establishing limits on the fat content of additional meat food products over time.

The Department also received a comment challenging the proposal from the opposite perspective: a public interest organization criticized the Department's proposal to restrict fat and protein content requirements to one category of product. This commenter asserted that in establishing a category of product as to which there are no fat or protein content requirements, the Department reverses its original 1978 conclusion and rejects the Panel's

recommendations. It was argued that the net effect of the proposal will be to increase the amount of animal fats available for use in food products because the greater amounts of fat allowed in product for processing would displace animal fat now used in processed meat food products and that fat would (because of expected lower cost) be used in other foods where vegetable fats are now used. According to the commenter, this was the reason the Panel recommended that the fat content of mechanically separated product, as well as that of finished products in which it is used, be limited. In addition, this commenter took the position that, while construction of a category of product for processing is unwarranted, it also is a mistake not to propose a specific protein standard for this category of product because unless one is spelled out, it can never be legally controlled and because the Department should not rely on the new, almost experimental, quality control systems to prevent dilution during processing; instead, protein standards should be incorporated, at least on an interim basis while factual data can be developed as to whether quality control systems can provide adequate protection.

The Department disagrees with this commenter's interpretation of the Panel's report on fat content. While the Panel subcommittee that addressed this issue acknowledged that the net result of use of mechanically separated product may be to have more animal fat available for use in the American diet, the subcommittee went on to state that it also is to be expected that theoretical net increases will be moderated by the displacement of one meat food product in any given meal by another. (The Panel's report did not discuss potential effects on the vegetable fats used in other foods. It also should be noted that insofar as the raw materials for mechanical deboning already are available for use to produce animal fats, the extent of any such effects is questionable.) Moreover, the Panel rested its recommendations not on this factor, but rather on concern over the general problem of excessive intakes of fat and their effect on health; and its recommendation was that the fat content of mechanically separated product be limited on the basis of good manufacturing practices, not that any particular, single limit be imposed.

As the Department noted when it first proposed a single limit of 30 percent for all mechanically separated product, the Panel "was reluctant to approve a product that would increase the total fat

composition of meat products in which it was used." 42 FR 54437, 54439. The Department imposed this single limit as part of its decision to establish only one category of mechanically separated product, rather than follow the multiple class approach of its first proposal (which would have allowed an unlimited amount of the top class of the product to be used in meat food product formulations). That decision rested, among other things, on the absence of limitations on the fat content of a number of meat food products in which mechanically separated product is a suitable ingredient. 41 FR 17560, 17562; 42 FR 54437, 54440. The Department has concluded that its two category approach, with the associated use limits in § 319.6 of the regulations (9 CFR 319.6), will continue to satisfy the concerns raised in the prior rulemaking.

The Department also does not agree with this commenter's position on protein content. The purpose of the proposal to establish a category of product for processing was to permit variability in product composition. The Department did not intend, therefore, to attempt to enforce any particular minimum level of protein content. Instead, its concern was that there be sufficient protection against decreases in the protein content of finished meat food products when product for processing is used as one of the livestock ingredients.

The amended regulations permit use of product for processing only in meat food products which are subject to definitions and standards that limit finished product fat content. Because livestock products are composed essentially of fat, protein, and water, and fat and protein content tend to be inversely related to at least some extent, these limits on fat content operate to some degree as an indirect control on the protein content of such meat food products. As noted by one commenter, the definitions and standards for these meat food products also control the use of added water (see, e.g., 9 CFR 319.145(b)(2) and 319.180(a)), providing another indirect control.

These controls will protect finished product quality so long as the mechanical deboning operation does not, through the introduction of extraneous sources of water, result in the dilution of mechanically separated product. While this possibility exists, the Department is not aware of any significant dilution problem to date, and it has concluded that it can prevent such problems in the future through the plant quality control system approach already in the regulations (9 CFR 319.5(e)(2)).

Production of MS(S) under an approved plant quality control system is a regulatory prerequisite for the approval of labels for all MS(S) and products in which it is used. In order to be approved, such systems must provide the controls necessary to assure the production of complying product in accordance with good manufacturing practice. Such controls include adequate procedures for cooling the product during the manufacturing process without causing dilution with water.

Finally, the Department does not agree with this commenter's criticism of its reliance on a quality control approach. Although the Department's formalized program for plant quality control was instituted on an industry-wide basis less than 2 years ago (45 FR 54310, August 15, 1980), this step was preceded by about 15 years of experience evaluating industry members' use of various methods and systems to control their procedures and products within certain specifications and utilizing the information they generate in assuring compliance with regulatory requirements. Moreover, the potential for product dilution is an area with which the Department and the regulated industry have had a great deal of experience.

Therefore, the Department has concluded that current regulatory controls should be adequate to protect the quality and expected characteristics of meat food products in which product for processing may be used as an ingredient and additional regulatory controls are not warranted. Based on these conclusions, the Department is adopting the portion of its proposal establishing two categories of MS(S) and restricting use of the second category (product for processing) to meat food products that are subject to regulatory definitions and standards which limit finished product fat content (9 CFR 319.5(a) and 319.6(c)).

(e) Protein quality.

The Department's proposal retained the minimum protein quality requirement—a Protein Efficiency Ratio (PER) of 2.5 (9 CFR 319.5(a))—as well as the acceptability of an essential amino acid content of at least 33 percent of total amino acids as evidence of compliance with that requirement (9 CFR 319.5(e)(1)). The Department did, however, propose amendments to (1) permit use of product failing to meet the minimum protein quality requirement only in producing animal fats and (2) clarify the compliance provision by specifying the amino acids included in a calculation of total amino acids. 46 FR 39274, 39286. The Department has concluded that these amendments should be adopted. It has also

concluded that two further amendments should be adopted in order to control the costs of measuring compliance with this requirement and to simplify the compliance provision.

Thirty-three comments addressed protein quality issues. Almost all of these comments were submitted by industry-related individuals and groups. Comments from academia and a public interest organization were among the others received. Most of those commenting on the protein quality requirement agreed that it is reasonable and appropriate for a product used as a meat ingredient. However, a number of commenters questioned various aspects of the existing regulatory provisions implementing this requirement. Generally predicated their position on the expectation that the protein quality requirement consistently or almost always will be met, and in some cases on the premise that protein consumption is not a problem in the United States, these commenters focused their concern on the costs associated with these provisions. Their comments fell into two categories: Criticism of not permitting product failing to meet the protein quality requirement to be used for purposes other than producing animal fats (9 CFR 319.5(a)) and criticism of the provisions for assuring compliance with the protein quality requirement (9 CFR 319.5(e)(1) and (2)).

Commenters making the first criticism argued that it would be wasteful to restrict use of noncomplying product to rendering or other inedible uses. They suggested various alternatives. These included not restricting use of the occasional noncomplying lot at all, basing regulatory action on a moving average of a PER of 2.5, permitting use of noncomplying product in meat food products such as soup stocks where its lower protein quality would not affect nutritional quality, and permitting blending to bring noncomplying product into compliance. However, none of these comments objected to the Department's proposal to delete the use of product failing to meet the protein quality requirement as an imitation of the standardized product. Thus, the comments did not evidence any industry interest in the production of "Imitation MS(S)" for use in the formulation of imitation meat food products.

Nor did any of the commenters disagree with the Department's proposal to retain and clarify the amino acid content alternative to the PER assay for demonstrating compliance with the protein quality requirement (although one commenter said that while this alternative measure does give an approximation of protein quality, it does not correlate well with all PER values).

Instead, criticism of the compliance provisions was directed at the time and expense they involve, particularly for PER assays and particularly for small businesses. Thus, while a few commenters supported amino acid content measurements as less onerous than PER assays, the need for any protein quality testing was questioned, at least on a long term basis. Some commenters suggested reducing or eliminating the testing requirements in the quality control provision as soon as a broader data base confirms mechanically separated product is a high quality protein source, with one commenter recommending these requirements be expressly limited to an initial period of 12 to 24 months and one recommending that they be replaced by a surveillance system that could soon assure that the protein being recovered is from skeletal meat. Another commenter suggested restricting the livestock parts that can be processed by mechanical deboning as an alternative to testing the product.

While the Department does not anticipate that processors following good manufacturing practices will have difficulties complying with the protein quality requirement and it understands the concerns of these commenters, it does not accept their proposed alternatives. The Department's expectations and concerns already are reflected in its determinations regarding limitations on the use of MS(S) and its decision to rely on an approved plant quality control system as the principal regulatory control, with limited testing to verify compliance with this part of the product standard: A processor's primary responsibility is to prevent problems from arising by controlling the ingoing ingredients and the operation of the deboning equipment. He or she need only analyze a maximum of one lot of MS(S) per month to check the effectiveness of these controls and, once their effectiveness is confirmed over a 3 month period, subsequent analyses need only be performed once every 6 months so long as the product is in compliance. Thus, instead of limiting the livestock parts that may be used as raw materials for mechanical deboning, the selection of appropriate livestock parts (including combinations of different parts) is left to the processor; and instead of requiring continual testing to confirm that the resulting product complies, confirmatory analyses need only be conducted periodically. (Given this testing rate, there is not adequate data to support a moving average approach.)

Should these test results reveal that a processor's primary controls have

proved to be ineffective, however, the Department cannot simply ignore them and permit the tested lot to be used as if it complied. This would be no more appropriate than occasionally permitting more bone in MS(S) than is allowed under the standard or occasionally permitting processors knowingly to formulate other products in violation of the standards which apply to them. The law is clear on this point: A product is misbranded if it is offered for sale under the name of another food or if it purports to be or is represented as a food for which a definition and standard has been prescribed unless it conforms to that definition and standard (21 U.S.C. 601(n) (2) and (7)). "MS(S)" is a product with a minimum PER of 2.5. Product not meeting this provision of the definition and standard cannot be marketed as "MS(S)". Moreover, if the Department were to modify the standard's requirement that product resulting from the mechanical separation and removal process must contain high quality protein in order to be called MS(S) and be used in the formulation of meat food products, it would be diminishing processors' incentive to assure that the products they manufacture comply with this requirement.

The Department is not rejecting the other suggestion put forward in the comments: that processors be permitted to blend product not meeting the protein quality requirement with other, complying product. As indicated above, when a lot of MS(S) fails to meet this requirement, it means that the primary control—the plant's quality control system—has not been effective in assuring compliance. Quality control plans provide for corrective steps to be taken in such situations. If a plant wishes to include among those actions provisions for the reprocessing of the tested lot to bring it into compliance, rather than use the tested lot in producing animal fats, it may do so. Because the tested lot has not been rejected for safety reasons (e.g., presence of a poisonous substance or production under insanitary conditions), blending may be appropriate. Therefore, the Department will consider any such proposal and approve it if, but only if, it comports with all relevant requirements (e.g., 9 CFR 318.18) and assures that the reprocessed product conforms to the definition and standard in all respects (9 CFR 319.5).

The Department's belief in the appropriateness of its existing requirements also is supported by the continuing concern of some about the quality of the protein in this new product as compared with that of meat.

As stated by one commenter, this concern reflects an expectation that mechanically separated product will contain a large amount of connective tissue and, consequently, of collagen, an incomplete animal protein lacking in the essential amino acid tryptophan. Citing research it sponsored during the Department's prior rulemaking on this product, this commenter concluded that the use of mechanically separated product would result in nutritional dilution. Two other commenters contended that there is no cause for concern because collagen is discarded by mechanical deboners along with the bone (with one stating that even if collagen were higher, a protein quality requirement would not be needed because mechanically separated product is high in protein quality, it is used in conjunction with meats high in protein quality, and consumption of enough high quality protein is not a problem in the United States). Research also was cited to support the position that the protein quality of mechanically separated product is comparable to that of meat and that it has a PER equal to or greater than 2.5.

No data or information that was not available to the Department in 1978 was submitted on either side of this issue. The Department continues to ascribe to the position that its regulatory requirements can be readily attained and complying product has protein of high quality. 43 FR 26416, 26421. However, the conclusion that problems are not to be anticipated was predicated on the assumption that the product standard will be enforced. Therefore, the Department is retaining the quality control provisions that bear on protein quality (9 CFR 319.5(e)(2)). Moreover, as explained below in the discussion of use limitations (9 CFR 319.6), in any future reconsideration of whether to permit the usage level of MS(S) to exceed 20 percent of the livestock and poultry product portion, the Department plans to pursue further questions regarding possible effects on the tryptophan content of meat food products in which MS(S) is the sole or major livestock ingredient.

In addition, the Department is making two further changes to control the costs of monitoring protein quality and to simplify the compliance provision (9 CFR 319.5(e)(1)). The first of these changes is the deletion of the nonessential amino acid cystine from the calculation of total amino acids. In response to comments contending that verifying compliance with the protein quality requirement would be burdensome, the Department reviewed

the procedures needed to determine the percent that essential amino acid content is of total amino acid content. This review indicated that quantitative estimation of cystine is difficult and costly because during the acid hydrolysis step used to prepare protein samples for amino acid analysis, cystine undergoes oxidative degradation, producing a series of products all of which must be totalled to estimate the cystine content of the protein sample. Accurate measurement of the cystine content of a protein requires conversion of all cystine to a single substance (cystic acid) by oxidative treatment of a separate sample of the protein. This treatment partially destroys many of the other amino acids in the sample, rendering it inappropriate for estimation of nearly all other amino acids. Therefore, the method which accurately measures the other amino acids included in the regulatory provision does not provide an accurate measure of cystine content without an additional sample analysis. As a result, exclusion of cystine from the calculation of total amino acids will cut in half the number of analyses required and thereby reduce significantly the cost of verifying compliance with the protein quality requirement. (A number of private laboratories charge approximately \$150 for analyzing a protein sample for all of the amino acids other than cystine that are included in the regulatory provision, and approximately \$50 more to analyze an additional sample for cystine content. Thus, this change reduces testing costs by approximately 25 percent.)

As cystine is not an essential amino acid, it is included only in the denominator of the ratio in the provision—total amino acid content—and does not affect the numerator of the ratio—essential amino acid content. The Department has concluded, however, that excluding cystine would, at most, result in a slight increase in the percent that essential amino acid content is of total amino acid content. This determination is based on a review of data on the amino acids present in various proteins in meat and in the samples of mechanically separated beef evaluated by the Panel in 1977. These data confirm that the cystine content of such proteins is low. For example, in myosin and myoglobin, the major skeletal muscle proteins, cystine either is absent or present at a level of about 1 percent of the total amino acids present. Moreover, collagen is devoid of cystine. Therefore, excluding cystine will not mask the presence of high levels of collagen. (Hydroxyproline, proline, and

glycine, which are found in greater amounts in collagen than in muscle proteins, are included in the calculation.) In the samples of mechanically separated beef evaluated by the Panel, the average cystine content was 1.5 to 1.6 percent of the total amino acids present.

The Department also applied the compliance provision to the amino acid data on these samples of mechanically separated beef. When cystine content was included in the calculation, the mean value for essential amino acid content was 40.19 percent of total amino acids (and none of the values fell below the minimum criterion of 33 percent). When cystine content was excluded, the mean value was 40.85 percent. Thus, the deletion of cystine content produced a mean increase of 0.66 percent. Because the relationship between this measure and actual protein quality is an imprecise and indirect one, a mean difference of 0.66 percent does not have any practical impact on the results obtained.

Based on this review, the Department has concluded that the provision need not be further modified to reflect this change. Furthermore, because this change is restricted to the method used for assuring compliance with the regulatory criterion and does not have any substantive effect on the criterion itself, the Department has determined that it can be incorporated as part of this final rule.

The Department also is willing to consider the possibility of reducing costs further by eliminating the periodic testing requirement if and when it is demonstrated that such testing no longer is needed to verify compliance with the protein quality requirement. However, it does not agree with the commenter who asked that an explicit time limit be placed on the periodic testing requirement as part of these amendments, without first evaluating additional data on the protein quality of MS(S).

The Department is actively investigating the protein quality of livestock and poultry products, including the identification of accurate and cost-effective methods for determining protein quality. Depending on the results of that investigation, the Department will evaluate whether the method for protein quality determinations should be modified. During the pendency of the investigation, the Department is willing to reevaluate the need for periodic testing to verify compliance with the protein quality requirement on the basis of additional data on the protein quality of MS(S). Persons interested in the subject are hereby notified that the

Department is prepared to cooperate with them in designing the appropriate procedures for collecting and analyzing data on this question.

The second change being adopted by the Department is to simplify the compliance provision by focusing solely on the comparison that is to be made between essential amino acid content and total amino acid content. The first sentence of the provision clearly states the criterion to be met when this comparison is used as evidence of compliance with the protein quality requirement: an essential amino acid content of at least 33 percent of the total amino acids present. To apply this provision, the only additional information needed is the particular amino acids to be considered. Therefore, the Department is restricting the second sentence of this provision to a specification of the 7 essential amino acids to be included in "essential amino acid content" and the 17 amino acids to be included in "the total amino acids present".

(f) Quality control.

The Department proposed modifying the regulatory requirements for quality control systems in establishments producing mechanically separated product (9 CFR 319.5(e)(2)) to (1) incorporate the provisions regarding applications for plant quality control, their evaluation and approval by the Administrator of FSIS, and the conditions and procedures for terminating approval that were promulgated by the Department on August 15, 1980 (see 9 CFR 318.4 (d) (1) and (2), (e), and (g)(2)), (2) permit the use of Chemistry Laboratory Guidebook methods if no AOAC (Association of Official Analytical Chemists) method is available and provide for the submission of alternative methods of analysis to the Administrator of FSIS to determine their acceptability, (3) clarify the quantity of product which may constitute a "lot", and (4) restrict the provisions designed to assure compliance with fat and protein content requirements to product which purports to meet such requirements. 46 FR 39274, 39286-87. The Department has concluded that all of these amendments should be adopted for the reasons stated in the proposal. In addition, the Department is further amending the quality control requirements to clarify that compliance with the bone particle size limit can be assured by methods other than laboratory analysis and to clarify that, in monitoring compliance with the protein quality requirement, either PER assays or amino acid content analysis, but not both, must be performed.

Twenty-three comments addressed quality control issues. All of these comments were submitted by industry-related individuals and groups; and only one of them addressed any of the modifications proposed by the Department. That commenter said the proposal to clarify the quantity of product which may constitute a lot seems adequate for the purpose of this regulation in that it sets a reasonable maximum limit and allows establishments to choose to use a smaller lot size.

After reviewing this and other comments, which are discussed below, the Department determined that the regulatory requirements for quality control systems in establishments producing MS(S) should be amended as proposed for the following reasons: The first amendment incorporates certain of the Department's regulatory provisions for plant quality control in order to facilitate the development and maintenance of appropriate quality control programs for producing MS(S) by providing greater specificity as to the procedures and criteria for assessing the adequacy of such programs. This amendment also will facilitate the integration of plant quality control under this regulation with any other, voluntary plant quality control programs that manufacturers choose to operate. (The information collection requirements regarding plant quality control have been approved by the Office of Management and Budget (OMB). The OMB approval number is 0583-0015.)

The second amendment expands the types of analytical methods that may be used in determining compliance with the product standard. This is being done because official AOAC methods do not exist for all of the analyses required by the regulation and in order to increase the regulation's flexibility by providing for the approval of alternative methods which yield accurate and reliable data. The amended regulation also incorporates citations to current AOAC and chemistry Laboratory Guidebook methods, and it tells the public where it can obtain copies of these methods. (Errors in certain of these citations as they appeared in the proposal have been corrected in the final rule. A notice of any change in these methods will be published in the Federal Register.) The third amendment clarifies that, as used in this regulation, a "lot" constitutes the quantity of product designated as such by the establishment from the product produced from a single livestock species in no more than one continuous shift of up to 12 hours. The fourth amendment is necessitated by the Department's

decision to include within the definition and standard a category of product as to which there are no fat or protein content requirements. The absence of such requirements means that chemical analyses to verify the fat and protein content of product for processing are not needed to determine its compliance with the product standard. Therefore, these analyses are limited to product which is represented as containing not more than 30 percent fat and not less than 14 percent protein.

Most of the other comments addressing this portion of the product standard focused on how processors should assure that MS(S) meets the bone particle size limit, the testing needed to verify that MS(S) meets the protein quality minimum, and/or the requirement that a plant quality control system must include methods "to maintain uniformity of the raw ingredients" used in manufacturing MS(S). As noted above, most of those commenting on the bone particle size limit were more concerned with the compliance aspect of this requirement than with the limit itself. These commenters' basic position was that processing establishments should not be required to test for bone particle size on an ongoing basis; instead, compliance should focus on the equipment to be used in manufacturing MS(S). In support of this position, several of them questioned the ability of processors to test accurately for bone particle size, said that enforcement through testing would be difficult and burdensome because such analyses cannot be conveniently accomplished at the processing plant level, and/or argued that there is no need for expensive testing once equipment is approved. It was contended that bone particle size is a function of equipment design and apparently does not vary significantly with other factors such as heat, pressure, or wear. Therefore, some commenters recommended that the Department control the size of the openings in the screens or other equipment used in making the product or that the Department allow use of any equipment—including types which do not employ screens or other straining devices—shown to yield product meeting the bone particle size requirement. In addition, several commenters said that the bone particle size control should be implemented as part of the Department's equipment approval process; and one suggested that this be accomplished through field tests and the submission of test data to support requests for approval, with USDA devising a mechanical and visual

method for inspection at the point of production.

As one commenter noted, the Department's first proposal for controlling bone particle size was stated in terms of a limit on the size of the openings in the screens, sieves, or ports through which product resulting from the mechanical separation and removal process is strained. 42 FR 54437, 54441. This provision was included in response to the Panel's recommendation that bone particle size be limited to the levels then associated with good manufacturing practice. 42 FR 54437, 54440. Because the bone particles evaluated by the Panel and found to present no hazards to health had been produced by equipment with openings not exceeding 0.5 mm in diameter, the proposed rule incorporated this dimension as the maximum size for equipment openings. 43 FR 26416, 26422. In the final 1978 rule, the Department replaced this maximum with a limit on the size of the bone particles that resulted from use of such equipment in accordance with the proposed procedures. The purpose of this change was to avoid discouraging the development of equipment that does not employ screens, sieves, or ports by focusing on the size of the bone particles produced rather than the characteristics of the equipment used. 43 FR 26416, 26422.

The Department did not intend this modification of the product definition (9 CFR 319.5(a)) to be interpreted as imposing a requirement that the resulting product must be tested as part of any quality control system approved under § 319.5(e)(2) of the regulations (9 CFR 319.5(e)(2)). The processors responsibility is to assure that the product complies with the bone particle size limit. The most important factor affecting bone particle size is the type of equipment used. Protection against use of inappropriate equipment already is provided by the equipment approval process implemented in § 308.5 of the regulations (9 CFR 308.5): To be used for preparing any edible product or ingredient, equipment must be of such material and construction as, in the judgment of the Administrator of FSIS, will avoid adulteration and misbranding of such product. When equipment is proposed for use in an official establishment, the Administrator specified the information (to be submitted by the establishment operator) that is necessary to determine whether these criteria are met and then evaluates that information to determine the acceptability of the equipment model for its proposed use. (A copy of

the listing of equipment that has been evaluated and found acceptable for use in mechanically deboning livestock carcasses can be obtained from Technical Services, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.)

The role of the quality control system in assuring complying product focuses on the operation of equipment that has been found to be acceptable: Any conditions for use prescribed as a result of evaluation during the equipment approval process must be followed. Use must accord with good manufacturing practice. Other factors that affect bone particle size (e.g., the wearing down of parts, the level of pressure applied) must be controlled. Methods other than laboratory testing should be adequate to verify the effectiveness of these controls. However, as the processor remains responsible for any violation that does occur, he or she may wish to analyze samples of the product, particularly during the initial periods of operation of newer types of equipment. Those interested in reviewing the methodology the Department currently uses in its analyses to verify compliance with the bone particle size limit will find a copy of the procedures in the record of this rulemaking.

In view of the comments on this issue, the Department reviewed the quality control provision and determined that it should be clarified to avoid future misinterpretation by the public. Therefore, it is amending the fourth sentence of § 319.5(e)(2) of the regulations (9 CFR 319.5(e)(2)), which describes the methodological requirements for quality control systems, to include language specifically providing for procedures for assuring compliance in addition to chemical analyses.

Comments on the testing needed to verify that MS(S) meets the protein quality requirement are addressed above in conjunction with the discussion of that requirement. As is indicated there, the Department does not believe that the testing requirement in the quality control provision should be modified at this time, but it plans to reevaluate this requirement in the future. The Department does believe, however, that here too a modification of the language used will prevent misinterpretation of this provision. Under § 319.5(a) of the regulations (9 CFR 319.5(a)), MS(S) must have a minimum PER of 2.5 except as modified by § 319.5(e)(1) (9 CFR 319.5(e)(1)), which accepts an essential amino acid content of at least 33 percent of the total

amino acids present as evidence of compliance with this requirement. While these provisions clearly indicate that either PER assays or amino acid content analyses may be used to verify protein quality, § 319.5(e)(2) of the regulations (9 CFR 319.5(e)(2)) can be read as requiring that both types of testing be performed because that provision refers to analyses to verify content of essential amino acids "and" protein efficiency ratio. To clarify that in monitoring protein quality, either one of these tests, but not both of them, must be performed, the Department is amending the two sentences that refer to such testing to require analysis of "essential amino acid content and/or protein efficiency ratio".

The last criticism of the specific requirements of the quality control provision was made by a few commenters who questioned the requirement that a plant quality control system must include methods to maintain uniformity of the raw ingredients. According to these commenters, this requirement is inappropriate because the raw ingredients used are not uniform; they vary with the species and parts of the livestock carcass and, there is no uniformity to be maintained.

The Department agrees with these commenters that diverse raw materials may be used in making MS(S). However, that very variation is the reason why this requirement is necessary. As indicated above, the Department is relying on an approved plant quality control system to assure compliance with the product standard, with only periodic testing to check the effectiveness of this control. The Department took this approach, rather than requiring continual testing of the product, to keep the costs of production down. In order that the results of the analyses that are conducted can be used in assessing whether or not the processing operation is, in fact, under control, the Department must be certain that the lots of MS(S) tested are comparable to those which are not tested. Therefore, the factors that can affect the characteristics of MS(S) must be controlled by the processor. These factors include such characteristics of the ingoing ingredients as the proportions of different parts of the carcass being used and the extent to which skeletal muscle has been removed by hand trimming before mechanical deboning. Thus, for example, if a processor wishes to make mechanically separated beef from certain parts of choice grade steers on some days and from other parts of utility grade cows on other days, he or she

should handle these under the quality control system as different types of MS(S).

In addition to the comments discussed above, several commenters expressed more general concerns about the quality control provision. Some of these comments evidenced confusion about the types of establishments to which this provision applies or whether it applies unequally to processors who manufacture only mechanically separated product as compared with those who manufacture both mechanically separated product and finished meat food products in which it is used as an ingredient; and one argued that the provision is too complex. Others questioned the need for any quality control system in these regulations, with some contending that this requirement discriminates against the red meat industry because no such requirements are imposed on manufacturers of product made by mechanically deboning poultry carcasses.

The Department believes that the scope of this provision is clear: MS(S) must be produced by an establishment under an approved plant quality control system as a prerequisite for the approval of labels for the MS(S) itself or any product in which it is used as an ingredient. Therefore, only establishments manufacturing MS(S) must have such a quality control system. This provision does not apply unequally to different types of processors as it only covers the portion of their operations involving the manufacture of MS(S). The Department also does not agree with the comment that this provision is too complex. MS(S) is a product of advanced technology. To the extent that the provision for the quality control system regarding its production appears to be complex, this reflects the nature of the technological process involved in the manufacture of MS(S).

Finally, the Department continues to believe that the quality control provision is necessary and appropriate to avoid adulteration and misbranding and is not burdensome. It is the result of an extensive rulemaking which concluded that special requirements are needed to assure that establishments formulate this product to comply consistently with the requirements of the product standard and thereby avoid false or misleading labeling. 43 FR 26416, 26422. No new information challenging this conclusion has been brought to the Department's attention. No similar regulatory review of product made by mechanically deboning poultry carcasses has been conducted and, therefore, a comparison with the

regulation of that product is inapt. In addition, as Drs. Bullock and Ward noted in their analysis, the current regulations have a small impact on costs of producing this product. Insofar as any of these costs are attributable to the quality control provision, there are countervailing benefits to processors of MS(S): by providing controls and information that maximize the likelihood that product of consistent and uniform quality which complies with regulatory requirements will be manufactured at a predicted cost, quality control helps to minimize a processor's costs.

2. Handling Requirements

The Department did not propose changing the requirements established in 1978 for the handling of material for mechanical deboning and the handling of the product itself (9 CFR 318.18); and it has concluded that no amendments to these requirements are warranted. However, adoption of amendments to the product definition and standard necessitates changes to reflect the new product name and the elimination of "Imitation MP(S)P" as a product to be used in the formulation of imitation meat food products. 46 FR 39274, 39287. Therefore, the Department is amending this regulation by replacing the references to "Mechanically Processed (Species) Product" and "an imitation of such product" with the new product name—"Mechanically Separated (Species)".

Only 2 comments addressed the handling requirements for mechanically separated product. One commenter, an industry member, said that this product, as well as all meat products, should be handled in a manner best designed to assure it is wholesome, sanitary, and unadulterated; but he contended that consumers' interests could be protected without another layer of requirements through the inspection system and existing industry procedures. Another commenter, a veterinarian with a State inspection program, expressed reservations about mechanically separated product, stating that no adequate testing of shelf life and keeping qualities under normal market distribution methods appears to be accomplished.

In its prior rulemaking, the Department evaluated the microbiology of mechanically separated product and the opportunities that it and its production present for bacterial growth and spoilage. The Department concluded that microbiological standards are not appropriate and found no evidence of any bacterial hazard so

long as handling accords with good manufacturing practices. However, because of the potential rise in the temperature of this product during the mechanical separation and removal process and the fact that the product consists of small particles having more surface area than most meat food products, the Department concluded that special processing and storage requirements are warranted for the raw materials used to make the product and for the product itself. 43 FR 26416, 26419. The Department has reached similar conclusions in other situations in which the particular characteristics of a livestock product make its general processing requirements inadequate. Thus, it has prescribed treatments for various pork products to destroy trichinae (9 CFR 318.10) and established procedures for hermetically sealed canned products to assure proper cleaning, closure, and heat processing (9 CFR 318.11). The Department has received no additional information on the basis of which to modify its earlier conclusions. Therefore, it continues to believe that these provisions are necessary and appropriate to assure that MS(S) and products in which it is used are wholesome and unadulterated; and it continues to believe that these provisions, in combination with its other regulatory requirements and plant quality control, are adequate for this purpose.

3. Use Limitations

The Department proposed amending the limitations on the use of mechanically separated product (9 CFR 319.6) in accordance with the proposed amendments to the product definition and standard (9 CFR 319.5) and also to encourage the development of machinery capable of producing product with a lower bone content, as follows: (1) Use of product for processing would be restricted to 20 percent of the livestock and poultry product portion of meat food products that are subject to definitions and standards of identity or composition which limit finished product fat content and (2) the 20 percent restriction on the amount of product meeting maximum fat and minimum protein content requirements would be replaced with a set of limits—from 20 percent to 100 percent—based on the product's calcium content. 46 FR 39274, 39287-89. The Department has decided to adopt the portion of the proposal that would permit use of product for processing in meat food products subject to regulatory definitions and standards which limit fat content (9 CFR 319.6(c)). The Department's reasons for restricting use

of this category of MS(S) to certain standardized meat food products are discussed above in conjunction with amendments to § 319.5(a) of the regulations (9 CFR 319.5(a)). The Department also has decided to withdraw the portion of the proposal that would have permitted usage levels of MS(S) meeting fat and protein content requirements to increase above the 20 percent level as hard bone content—measured by calcium content—decreases (9 CFR 319.6(b)). This decision is based primarily on the Department's conclusion that, contrary to its belief when the proposal was published, use of MS(S) at higher levels could result in significant increases in the cholesterol content of meat food products, increases that consumers would not expect and could not evaluate without additional information. As use at up to the 20 percent level does not present this problem and this limit is unlikely to constrain production and use of MS(S), the Department has decided to retain the existing restriction and not to engage in further rulemaking at this time. It is, however, amending the regulations to clarify the basis on which the 20 percent restriction is to be calculated (9 CFR 319.6 (b) and (c)).

The Department did not propose changing the existing prohibitions against use of different species of mechanically separated product in meat food products required to be prepared from one species and against its use in certain meat food products, but it did propose amendments to clarify the mandatory nature of these provisions. It also proposed to simplify the regulations by deleting an unnecessary cross reference to the labeling requirements for meat food products containing mechanically separated product. 46 FR 39274, 39287-89. The Department has concluded that these proposed amendments should be adopted and that, in addition, the list of meat food products in which use of MS(S) is prohibited should be amended to clarify its scope (9 CFR 319.6 (a) and (d)).

One hundred and thirty-four comments addressed limitations on the use of mechanically separated product. More than half of these comments were submitted by industry-related individuals and groups. Many individual consumers also commented on this aspect of the proposal, as did a number of professionals and State government officials or agencies and a public interest organization.

Limitations on Product for Processing

The majority of these commenters objected to the imposition of maximum fat and minimum protein content

requirements on any category of mechanically separated product and, hence, to distinctions in use limitations based on the proposed two category approach. Insofar as such comments addressed the proposal to restrict use of product for processing to certain standardized meat food products, they are summarized above in the discussion of the Department's decision to establish a category of MS(S) as to which there are no fat or protein content requirements. Insofar as they addressed the proposal to permit usage levels to increase as bone content decreases, they frequently supported replacement of the current 20 percent restriction with a restriction based on calcium content for all mechanically separated product; and some of these comments challenged the Department's retention of the 20 percent restriction for product for processing as being without apparent justification. The Department's response to these comments is included in the following discussion.

Amount of Product Limitation

Most of those commenting on the proposal to replace the 20 percent use level restriction with a set of limits on calcium content supported a calcium content approach, but criticized specific aspects of the proposed provision implementing this approach. A few of these commenters said they support such a change in the basis for the restriction because it should encourage development of better technology, because it is more acceptable than the current regulation, or because the question of product quality with use above the 20 percent level is for the manufacturer and the industry, not the government. The 20 percent restriction also was criticized as without economic justification by a commenter who said it seems logical that the market place would resolve the use level issue as the success of processed products depends on repeat purchases by satisfied consumers, and the current limit might be restrictive and create costs with future technology.

The focus on these commenters' concern with the proposal was the maximum of 0.15 percent calcium for mechanically separated product to be permitted to constitute up to 100 percent of the livestock and poultry product portion of meat food products. This limit was characterized as unrealistic and restrictive; and it was challenged as without justification in that it is based on the allegedly arbitrary 20 percent use level limit in the current regulation. Most commenters criticizing the 0.15 percent proposal recommended that 0.22

percent, 0.25 percent, or a level between 0.20 and 0.25 percent be used instead. The first of these amounts received the most support, with some of the commenters reasoning that this is the same level of calcium that currently is allowed in product made by mechanically deboning turkey and mature chicken carcasses. In addition, a few commenters criticized the proposal to tie a set of maximums on calcium content to different use level limits, suggesting that use just be limited on the basis of calcium content; and a few favored basing the limit on the calcium content of finished products or on their meat portions, with one stating that use of an ingredient level limit would only restrict the carcass parts used. It appears, however, that at least some of those commenting on these issues did not understand the proposed provision. Thus, for example, some of the commenters thought the 0.15 percent maximum would apply to finished products or to their livestock and poultry product portion, rather than to just the mechanically separated livestock product; and others based their recommendations on the erroneous assumption that the Department's objective was to control the calcium content of mechanically separated product or of finished products, as opposed to the livestock bone content of finished products.

Several other commenters supported retention of the 20 percent restriction. These commenters generally based their position on maintaining the character or quality of meat food products in which mechanically separated product is used, with one stating that his company's data and testing show this to be a maximum level and pork sausage quality is not reduced with use of this level. Finally, one commenter took the position that in proposing to allow varying amounts of mechanically separated product depending on its calcium content, the Department reverses its prudent 1978 conclusions and proposes to permit a product that was not analyzed for health and safety by the 1977 Panel. This commenter contended that while the proposed 0.15 percent calcium maximum may deal with the health problems stemming from the greater content of certain metals and other elements in the product, it does not address the greater problems of nucleic acid and protein quality; thus, it presents an imprudent and unacceptable result for groups of consumers with certain health conditions—gout sufferers and other hyperuricemics, who must strictly limit nucleic acid consumption—and for the public at large because products with

mechanically separated product used at up to the 100 percent level could be expected (due to its collagen content) to be seriously deficient in the essential amino acid tryptophan, and it is unknown what other health problems could result.

As indicated above, the Department has decided to withdraw its proposal to permit use of MS(S) meeting fat and protein content requirements to increase above 20 percent of the livestock and poultry product portion. The reasons for this decision were not the focus of concern of those favoring the proposed calcium content approach. Therefore, the Department's primary goal in responding to those commenters is to clarify the issues involved in order to avoid further misinterpretation or misunderstanding in any future evaluation or discussion of this subject by reviewing the basis for the proposal and its limited purpose.

The calcium content approach to regulating use of mechanically separated product was developed in response to the PCMA-AMI petition, which advocated this approach as a means of providing a technology-forcing incentive to lower the powdered bone content of mechanically separated product. The only information submitted in support of this request to amend the regulations was the economic analysis of Drs. Bullock and Ward. They took the position that the current 20 percent limit does not appear to be generating social costs at present and is not likely to become an effective constraint on production or use of mechanically separated product. They nevertheless recommended that it be removed because it is without economic justification: consumer satisfaction should be relied on to weed out products containing too much mechanically separated product and the development of potential new products that might be acceptable with higher levels should not be precluded.

The Department accepted the value of encouraging technological developments that would increase the capability of deboning machinery to keep hard bone from passing through the equipment along with soft muscle tissue because a number of the health and safety, as well as quality, issues presented by mechanically separated product are associated with its bone content. The Department did not accept, however, the apparent assumption that consumer satisfaction considerations are the sole basis for the current use level limit. As just noted, this is not the case: among other things, the 20 percent restriction, in combination with the 0.75 percent

maximum on the calcium content of MS(S), limits the hard bone content of finished products and, hence, their content of substances which may concentrate in livestock bone (e.g., fluoride and lead). No new information was submitted on this aspect of the restriction. Therefore, the basic premise on which the proposal to permit higher use levels rested was that the livestock bone content of no finished meat food product would be any higher than is permitted under the existing regulations. 46 FR 39274, 39288-89. Of course, this premise also was essential to assuring that the proposed provision would fulfill its underlying objective: the provision would not function as an incentive to develop deboning equipment capable of separating out and removing more bone if manufacturers could use MS(S) at higher levels without a concomitant decrease in bone content.

The regulations employ calcium content as a measure of hard livestock bone content and they permit mechanically separated product with a calcium content of 0.75 percent to constitute no more than 20 percent of the livestock and poultry product portion of any meat food product. The same amount of livestock bone would be present if mechanically separated product with a calcium content of 0.15 percent were used as 100 percent of that portion. Therefore, use of MS(S) at the 100 percent level would be inconsistent with the premise underlying the proposal if its calcium content exceeded 0.15 percent, as recommended by a number of commenters, because it would result in an increase in the bone content of finished meat food products. Thus, for example, if MS(S) containing 0.22 percent calcium were used as 100 percent of the livestock and poultry product portion of a hotdog (which is 85 percent of the finished product), it could contain approximately 50 percent more livestock bone than permitted under the existing regulations or the proposal (i.e., 0.22 percent calcium in 85 percent of the hotdog would contribute 0.187 percent calcium, or up to 0.75 percent hard bone, whereas either 0.75 percent calcium in 17 percent of the hotdog (20 percent of 85 percent) or 0.15 percent calcium in 85 percent of the hotdog would contribute 0.1275 percent calcium, or up to 0.51 percent hard bone).

By the same token, the particular calcium content limits used in the current and proposed regulations reflect determinations about the maximum amount of hard livestock bone and accompanying substances in product made by mechanically deboning livestock carcasses, and not an effort to

control the amount of the essential nutrient calcium that is provided by meat food products. Therefore, it would be inappropriate here to apply this restriction so as to include or reflect the calcium contributed by any ingredient other than MS(S), as also was suggested by some commenters (e.g., product made by mechanically deboning turkey and mature chicken carcasses, which contains only up to 0.235 percent calcium).

In these circumstances, the proposal to permit use at higher levels represented a potential for the future—for the development of acceptable new products and for increased use levels in existing products with improvements in the deboning technology and with the application of that technology to whole livestock carcasses or parts from which most of the skeletal muscle has not first been removed by hand deboning. The Department proposed to provide that potential to the extent that, based on the available information, it appeared that limits on calcium, fat, and protein content could be relied upon to prevent potential health and safety problems and maintain the nutritional quality of finished products. 46 FR 39274, 39287-88. (See also the discussion of the amendment to § 319.5(a) of the regulations (9 CFR 319.5(a)) establishing a category of product for processing.)

Moreover, despite its decision to withdraw the proposal to permit use of MS(S) meeting fat and protein content requirements at higher levels, the Department disagrees with the criticism by one commenter that this proposed amendment is a reversal of its 1978 conclusions and would permit a product not analyzed by the 1977 Panel. First, the Department believes that the proposal was consistent with the Panel's evaluation of the health and safety aspects of the use of mechanically separated product. Insofar as the Panel considered the amount of this product that might be used, the focus of its concern was the potential effects of the product's hard bone content on dietary intake levels of substances (e.g., fluoride and lead) that are found in higher concentrations in the skeletal portion of livestock than in muscle tissue. Thus, the major issue here for the Panel was the extent to which use of mechanically separated product as an ingredient could be accompanied by consumption of hard bone and, hence, increased levels of these substances in the total diet, not the proportion (let alone the absolute amount) of any given meat food product that may consist of mechanically separated product. The proposal would not have permitted any

increase in hard bone consumption over the maximum allowed under the existing regulations and, therefore, does not reflect a reversal of the Department's earlier position regarding the need to prevent unsafe increases in dietary intake levels of various substances evaluated by the Panel.

Second, the evidence does not support this commenter's contentions regarding the health problems of use of mechanically separated product for gout sufferers and other hyperuricemic individuals due to MS(S)'s content of bone marrow and, hence, nucleic acids. Nucleic acids—deoxyribonucleic acid (DNA) and ribonucleic acid (RNA)—are complex molecules made up of the purines adenine and guanine plus many units of other compounds (e.g., sugar, phosphate). They are broken down into these components in the body. Purines, which also are found in free form, are further broken down to form uric acid. Because high purine intakes may increase blood and urine uric acid levels, they may be of concern in conditions, such as gout, where there is either a reduced ability to excrete uric acid or an increased endogenous production of uric acid. Thus, the appropriate focus of interest here is purine content. Moreover, the issue is whether the use of mechanically separated product would present an increased risk for these hyperuricemic individuals as compared with the mix of livestock products now used as ingredients in meat food products, not the absolute levels of these substances in mechanically separated product. Livestock products are recognized as sources of nucleic acids and purines.

Because increases in the levels of mechanically separated product might be accompanied by increases in the levels of bone marrow in meat food products and in response to the concern expressed by this commenter in the prior rulemaking regarding the nucleic acid content of bone marrow, the Department evaluated the available data before publishing the proposal and found no reason to believe that use of mechanically separated product in compliance with either the existing or proposed regulations would present an increased risk for gout sufferers or other hyperuricemic individuals. However, in view of the nucleic acid levels reported in a recently published article (P. Arasu, *et al.*, *Journal of Food Science*, 46:1114, 1981) and its desire to obtain additional information on this subject, the Department solicited further data and comments on the relative purine and nucleic acid contents of meat and mechanically separated product (46 FR

39274, 39289); and it collected and analyzed samples of mechanically separated product from all plants producing the product in August 1981. No further data were submitted by the public during the comment period.

In the Department's study, pairs of samples of mechanically separated beef and beef or pairs of samples of mechanically separated veal and veal from four processing plants were analyzed for purine content (adenine, guanine, hypoxanthine, xanthine, and total) and nucleic acid content (DNA, RNA, and total). Consistent with previously available data, the total purine content of mechanically separated product was found to be similar to that of meat. A difference of 10 percent is judged to be of little or no metabolic importance. The mean levels found in mechanically separated beef as compared with beef were well within 10 percent of one another. There was greater variation in the data on mechanically separated veal as compared with veal: the mean could be anywhere in the range between 5 percent lower and 27 percent higher. Even if one assumes the uppermost value of 27 percent higher total purine content, a meat food product could contain mechanically separated veal at up to the 37 percent usage level without being more than 10 percent higher in total purine content than a similar meat food product formulated without mechanically separated veal; and if a meat food product is formulated with mechanically separated veal at the 20 percent level, the potential increase in total purine content would be only 5 percent with the potential difference ranging from 1 percent lower to 5 percent higher). The greater variability, and higher total purine levels, found in livestock products made from veal carcasses is not surprising in view of the young age at which such animals are slaughtered. Rapid cell formation, rapid growth, rapid development, and stress, and hence higher bone marrow and total purine levels, characterize young animals.

In general, any diets that restrict purine intakes are based on total purine content. There should be no difference in the impact on such diets of consuming mechanically separated product as compared with meat. However, in view of the variation in the currently available data on mechanically separated veal and the potential those data indicate for increases in the total purine content of meat food products if mechanically separated veal were the sole or major livestock ingredient used, the relative purine contents of

mechanically separated veal and veal will be an issue in any future reconsideration of the 20 percent use limitation. Persons interested in pursuing such a reconsideration are hereby notified that the Department is prepared to cooperate with them in designing the appropriate procedures for collecting and analyzing data on this question.

In addition, research has shown that two individual purines—adenine and hypoxanthine—are of particular importance in raising blood uric acid levels (Clifford, *et al.*, *Journal of Nutrition*, 106:428-34, 1976). The average combined content of these two purines was lower in mechanically separated product than in meat. Hypoxanthine levels were lower in mechanically separated beef and mechanically separated veal than in beef and veal, respectively. Adenine levels were higher, but by amounts smaller than the differences in hypoxanthine content. The lower hypoxanthine levels should counteract the higher adenine levels in mechanically separated product, with no difference in impact from consumption of mechanically separated product than from consumption of meat. Differences in the proportions of the four individual purines found in mechanically separated beef and mechanically separated veal, on the one hand, and beef and veal, on the other, in part reflect differences in their nucleic acid contents: Levels of nucleic acids were higher in mechanically separated beef and mechanically separated veal than in beef and veal, respectively. However, as indicated above, relative purine levels are the appropriate focus of interest here.

Based on all of the information on this question, the Department has concluded that formulation of meat food products with mechanically separated product does not present an increased risk to gout sufferers and other hyperuricemic individuals, particularly in view of its decision to retain the 20 percent restriction on the amount of mechanically separated product that may be used in meat food product formulations. In this regard it also should be noted that current medical practices do not support view that gout sufferers and other hyperuricemic individuals must strictly limit their consumption of nucleic acids or purines. Drugs have been developed which are so effective in lowering serum urate levels that dietary restriction is seldom employed. Furthermore, if dietary management is used, recommended intake levels would require restricting

consumption of all livestock products (as well as many other foods).

The additional analytical work conducted by the Department did, however, raise a different concern. When the proposal was published, the Department believed that the cholesterol content of meat food products formulated with higher levels of mechanically separated product would not differ significantly from that of comparable meat food products formulated without mechanically separated product or with mechanically separated product limited to 20 percent of the livestock and poultry product portion. This belief was based on the findings in the Panel's report and, in particular, the finding that the cholesterol content of product made by mechanically deboning livestock varied within the same range as that of product made by hand deboning. But because the data reviewed by the Panel seemed to indicate potentially greater variability in the cholesterol content of mechanically separated product and were limited in scope, the Department noted its interest in receiving additional information on the relative cholesterol contents of ingredients made by mechanically and hand deboning livestock carcasses and parts. 46 FR 39274, 39285. No information was submitted by the public (although a few commenters did express concern about possible increases in cholesterol content). Recognizing that the Panel subcommittee which addressed this issue had suggested that periodic reevaluation might be desirable and in order to confirm its observation that there was no relationship between cholesterol content and total fat content, the Department reviewed the area.

The same samples of mechanically separated beef, mechanically separated veal, beef, and veal that were analyzed for purines and nucleic acids also were analyzed for cholesterol and fat content. In addition, the published literature on the relationships between cholesterol content and the component parts (i.e., spinal cord, bone marrow, muscle and fatty tissue) of mechanically separated product was reviewed. Evaluation of this information has led the Department to conclude that, based on all the data now available, it can no longer be said that the cholesterol content of product made by mechanically deboning livestock falls within the same range as that of product made by hand deboning. Instead, it appears that to the extent that mechanically separated product is made from materials which contain spinal cord and bone marrow (as opposed to hard bone) in addition to

muscle and fatty tissue, its cholesterol content will be greater than the cholesterol content of meat. In the samples analyzed by the Department, the mean cholesterol values for mechanically separated beef and mechanically separated veal were 209 mg and 239 mg per 100 grams, respectively, as compared with mean cholesterol values for beef and veal of 59 mg and 108 mg per 100 grams, respectively. Also, researchers at the University of Wyoming have found cholesterol levels in mechanically separated beef and mechanically separated pork that are higher than the representative values given for beef and pork (Field, R. A., "Mechanically Deboned Red Meat," *Advances in Food Research*, 27:23 80-81, 1980).

So long as mechanically separated product constitutes 20 percent or less of the livestock and poultry product portion, the cholesterol content of finished meat food products formulated with MS(S) will be only slightly higher than that of comparable products formulated without MS(S); and use of MS(S) will not lead to any appreciable increase in dietary cholesterol intakes. If, however, as the Department proposed, higher usage levels were permitted, the magnitude of the differences in cholesterol content could easily become quite striking; and the use of MS(S) could result in significant increases in the cholesterol content of meat food products. For example, it is to be expected that persons who have been advised by their physicians to restrict their intake of cholesterol would have to modify the foods they consume if they included such products in their diets (e.g., by reducing their consumption of other foods of animal origin such as milk, eggs, or cheese). Finally, the information reviewed confirms the earlier observation that cholesterol content and total fat content are not positively correlated. (Thus, restricting the fat content of MS(S) would not serve as a means for limiting its cholesterol content.)

Because the Department did not anticipate this problem when it proposed to permit mechanically separated product to be used at higher levels, the proposal did not deal with the issues these potential differences in composition raise. The Department has decided not to engage in further rulemaking on these issues at this time, in large part because use of MS(S) in compliance with the existing regulatory restriction of 20 percent is unlikely to constrain production and use: at the current stage of product development, formulations that are satisfactory to the

vast majority of processors contain MS(S) at less than the 20 percent level. Moreover, developments in mechanical deboning technology and practices may affect the extent to which higher usage levels would be a cause for concern. For example, it is possible that the cholesterol values found in the samples recently collected by the Department are higher than those found in the samples evaluated by the Panel because the more recent samples were made from raw materials that had a lower proportion of meat to bone or because they had a higher proportion of spinal cord and/or bone marrow. Similarly, MS(S) produced by applying the mechanical deboning technology to whole carcasses or parts from which most of the skeletal muscle has not first been removed by hand deboning might well have a cholesterol content comparable to that of meat of the same species. As production of MS(S) increases, the Department expects that additional information relevant to these issues will be compiled. Persons interested in pursuing the possibilities for a reconsideration of this use limitation are hereby notified that the Department is prepared to cooperate with them in designing the appropriate procedures for collecting and analyzing data on the questions of concern here.

In addition, the public should be aware that in any future reconsideration of this use limitation, the Department plans to pursue further an issue raised by one of the commenters: possible effects on the tryptophan content of meat food products if MS(S) were used as the sole or major part of the livestock and poultry product portion. As indicated above in the discussion of the product definition and standard (9 CFR 319.5), the Department continues to ascribe to its 1978 position on protein quality: the regulatory requirements can be readily attained and complying product has protein of high quality. That assessment was based on the Panel's evaluation of protein quality issues and on an additional evaluation conducted as a result of comments submitted during the prior rulemaking on this product which criticized the Panel for not comparing the amino acid profile of mechanically separated product with that of the hand trimmed meat that it could replace. In response to this concern, the Department made such a comparison and found that, on a gram per gram of nitrogen basis, the amino acid content of mechanically separated product is comparable to values given for beef in "Amino Acids Content of Foods—Home Economics Research Report No. 4" and to more recent values

accumulated by the Consumer and Food Economics Institute-Science and Education Administration, USDA. 43 FR 26416, 26421.

In response to this commenter's concerns regarding the proposal to permit use to increase to up to the 100 percent level, the Department reviewed the available information on the relative tryptophan contents of beef and mechanically separated beef. This review confirms the basic conclusions drawn by the Department in 1978. (Thus, for example, because hydroxyproline, proline, and glycine—nonessential amino acids that are found in greater amounts in collagen than in muscle protein—are included in calculating the proportion of total amino acids that are essential amino acids, the presence of collagen in MS(S) will not be masked.) But it also led the Department to conclude that additional information should be obtained before permitting use of MS(S) at higher levels because the data currently available on mechanically separated beef (which were obtained from samples selected to reflect a wide range of PER'S) indicate that as the proportion of mechanically separated beef in a meat food product approaches the 100 percent level, the difference between that product's tryptophan content and the tryptophan content of a product in which beef is the sole livestock ingredient could become significant. The Department expects that the likelihood of such a result would be lower where MS(S) is produced from whole carcasses or parts from which most of the skeletal muscle has not first been removed by hand deboning and that as production of MS(S) increases and the mechanical deboning technology develops, further information on this question will be compiled. (As indicated above, the relative total purine contents of mechanically separated veal and veal also will be an issue in any such proceeding.)

Finally, the Department is amending the regulations to clarify the basis on which the 20 percent restriction is to be calculated. None of the comments addressed the Department's proposal to replace the phrase "meat portion" with "livestock and poultry product portion" (although one commenter misunderstood the proposed phrase as referring to the finished products in which mechanically separated product may be used). This change is being made in order to communicate more clearly the ingredients the phrase is intended to encompass: all ingredients derived from livestock or poultry carcasses, including meat byproducts and various poultry

products as well as "meat". 46 FR 39274, 39288.

Meat Food Product Limitations

None of those commenting on use limitations addressed either the proposal to clarify the mandatory nature of the existing prohibitions against use of different species of mechanically separated product in meat food products required to be prepared from one species or against its use in certain meat food products. Nor did they address the proposal to simplify the regulation by deleting an unnecessary sentence cross referencing the labeling requirements for meat food products containing mechanically separated product. The Department is amending the regulations to incorporate these proposed changes to § 319.6 (a) and (d) (9 CFR 319.6 (a) and (d)).

Those commenters who submitted views on these provisions instead addressed the existing prohibitions against certain uses of mechanically separated product, prohibitions that the Department did not propose to change. All but one of these commenters focused on the meat food products in which mechanically separated product is not a permitted ingredient. That commenter supported retention of the provision that meat food products required to be from one species shall not contain mechanically separated product of any other species.

Several commenters criticized the prohibition against use of mechanically separated product in baby, junior, and toddler foods. One of these commenters stated that the more efficient use of this product could be accomplished by changing the exclusion. The others took the position that the product's fluoride content does not justify the exclusion. They contended that, if anything, the additional fluoride provided by mechanically separated product would help to overcome inadequate intakes, with some referring to recommendations for supplementation of this essential nutrient to prevent dental caries or for proper bone development and/or to benefits for those in areas where the water supply is not fluoridated. One of these commenters also contended that the major portion of fluoride in this product may not be bioavailable, that consumption from the source would be relatively low, and that the Panel's evaluation of this issue was based on erroneous intake data and overestimated consumption by an order of magnitude (no information or data were submitted to substantiate these contentions). Another group argued that while the appearance of baby teeth

could be affected, health would not be affected and mottling to teeth is an unusual occurrence; and they and a third commenter said that the exclusion is open to question as years of experience with infant foods containing product made by mechanically deboning poultry carcasses have not produced any documented cases of mottling of teeth. Finally, one of these commenters said it would seem mechanically separated product could be used in infant foods if the ingredient statement indicated it is "a source of calcium and fluoride".

Several commenters, on the other hand, stated that they support this prohibition. Two of these commenters rested their position on the product's fluoride content, with one saying use in these foods should not be allowed until better data are available. One favored exclusion of the product from infant foods and other foods for special dietary use. Another commenter gave protecting small children as her reason for why mechanically separated product should not be sold.

The Department has reviewed the comments on the exclusion of mechanically separated product from baby, junior, and toddler foods, the materials referenced in those comments, and the Panel's evaluation of this subject. It has found no reason to reconsider this prohibition on the basis of currently available information. Like other essential nutrients, there is a range within which intakes of fluoride are both adequate and safe and beyond which adverse effects can occur; and this range varies with factors such as age. Permanent mottling of teeth can occur with excessive fluoride intakes during the period when the teeth are being formed—the "crown calcification" period (which lasts from about 4 months to 8 years of age). The decision that mechanically separated product should be excluded from baby, junior, and toddler foods reflects the Department's determination that there is not sufficient information to conclude that the regulatory restrictions on this product (i.e., the 0.75 percent calcium content limit in combination with the 20 percent use level restriction) are adequate to prevent this problem in infants on a nationwide basis. This determination recognizes that infants' fluoride intakes can vary greatly depending, among other factors, on the level of fluoride in their drinking water. For example, several cities in South Carolina appear to have high levels of naturally-occurring fluoride in their drinking water. According to the preliminary findings of a study by the South Carolina Health

Department and the Communicable Disease Center, Department of Health and Human Services, fluorosis exists in these areas. Addition of even an extremely small amount of fluoride to the diets of infants in areas such as these through use of mechanically separated product would not be prudent. It also should be noted that, while the Department has at this time made no decisions with respect to what further regulatory action to take regarding product made by mechanically deboning poultry, available data show only slight differences between the fluoride content of poultry meat and that of product made by mechanically deboning poultry other than mature female chickens (fowl); and data from the Department's Meat and Poultry Inspection Program indicate that only about 10 percent of the product made by mechanically deboning poultry was made from mature chickens in 1979.

The exclusion of mechanically separated product from various other meat food products also was challenged by a number of commenters. Some of these commenters advocated a general position, stating that use of mechanically separated product should be permitted in any meat food product in which chopped or ground meat normally would be used, can be used, or can be used in small quantities at functional levels or in natural proportions, or that its use should be permitted in those meat food products in which finely ground or comminuted meat or product made by mechanically deboning poultry can be used. Certain of these commenters gave examples of particular meat food products in which they believe use should be permitted and others focused their concern on the exclusion of mechanically separated product from particular meat food products. Thus, it was contended that use of mechanically separated product in restructured meat food products, sectioned and formed hams and other products, and fabricated steaks and roasts should be evaluated; and one commenter also supported allowing use in meat pies, beef with gravy, and lima beans with ham. Possibilities for cost savings, improved finished product quality, certain advantageous functional characteristics (e.g., good binding) of mechanically separated product manufactured with newer types of equipment, encouraging innovation, optimizing use of protein resources, and offering consumers a wider variety of products were reasons given in support of some of these uses. In addition, one commenter supported allowing use in ground beef, stating that proper labeling

ought to be the key; and another supported use in ground beef and/or hamburger, provided they are appropriately labeled, based on his erroneous belief that soy is permitted at up to a 30-percent level in such products (see 9 CFR 319.15 (a) and (b)). Finally, two commenters criticized § 319.15 of the regulations (9 CFR 319.15)—the standard for miscellaneous beef products—as restricting use of lamb and mutton products; and they suggested amending that section to permit use of mechanically separated product in any meat food product which includes finely ground or comminuted meat.

Two commenters disagreed with those calling for a reconsideration of some of these restrictions on the use of mechanically separated product. One of them stated that use of mechanically separated product in meat food products such as hamburger, chopped beef, and chopped steaks would significantly change their texture. He took the position that these products have been standardized for many years and the consumer has come to expect them to be the "better quality" ground beef products, and that inclusion of mechanically separated product would create a price difference between the traditional products and those made with this ingredient and the consumer would be deceived, particularly in advertising, because both products would bear the same name.

After reviewing these comments and the provisions of Part 319 of the regulations (9 CFR Part 319) bearing on the use of MS(S) as an ingredient, the Department still ascribes to the position that MS(S) is not an appropriate ingredient in certain meat food products. As the Department noted when, in 1976, it first considered the regulation of product made by mechanically deboning livestock carcasses and parts, the consumer purchases meat in two principal forms: One form is processed only to the extent of cutting or grinding. The other form is in processed meat food products in which manufacturing meats are mixed with other ingredients of animal and/or vegetable origin to form a new product. 41 FR 17560. The Department has consistently taken the position that product made by mechanically deboning livestock should not be included in meat food products sold in a form that is processed only to the extent of cutting or grinding (e.g., ground beef) or in processed meat food products that are convenience versions of cuts or solid pieces of meat (e.g., corned beef brisket, barbecued pork), but that its use should be permitted in processed meat food products that may

contain comminuted meat as well as other ingredients of animal or animal and vegetable origin. In other words, the Department's position has been and continues to be that its use should be permitted in processed meat food products where inclusion of this finely comminuted product would not be inconsistent with the basic characteristics, such as textural consistency, expected in such meat food products. See 42 FR 54437, 54440 and 43 FR 26416, 26422. Therefore, the Department does not agree with those commenters who suggested that use of mechanically separated product be permitted in products such as ground beef, fabricated steaks and roasts, or any product in which use of ground meat is permitted.

Nor does the Department agree with those commenters who suggested permitting its use in structured or sectioned and formed products such as hams. Such products frequently are associated with a particular cut of meat. To the extent that trimmings removed in the process of sectioning a cut of meat such as a ham are reincorporated in the shaping of the finished product, the product's constituents remain the same and it can retain the characteristics associated with that particular cut. The Department regards this as a distinctly different process than using product made by mechanical deboning as an ingredient. As stated above in response to comments suggesting that the product name identify mechanically separated product made from certain primal parts (9 CFR 319.5(a)), it is muscle meat and not any accompanying bone that characterizes primal parts; and product made from accompanying bones does not retain the distinctive characteristics of the cuts themselves.

In fact, the Department's review of this area has raised concerns about the appropriateness of the regulatory provisions which permit use of MS(S) in meat food products, such as pressed ham, chopped ham, and deviled ham (9 CFR 319.104(f), 319.105, and 319.760), that are represented as having been made from a particular part of the carcass. The Department's first proposal to regulate mechanically separated product would not have permitted it to be used as an ingredient in these meat food products. 41 FR 17560, 17566. While use was permitted in the 1978 regulations because the product's textural consistency would not impair finished quality, the Department now plans to reconsider these provisions in light of the concerns discussed herein.

The Department's review also has indicated that the scope of some of the

existing restrictions is unclear. In its prior rulemaking, the Department amended Part 319 of the regulations (9 CFR Part 319), the definitions and standards of identity or composition for meat food products. Mechanically separated product was added to the livestock products named as ingredients permitted in various meat food products where its use was to be allowed. Mechanically separated product was not added to such named ingredients where its use was not to be allowed, leaving the existing restrictions on the livestock ingredients permitted in such products intact. The list of meat food products included in § 319.6 of the regulations (9 CFR 319.6) was intended to reflect the Department's determinations regarding this latter category of meat food products, as well as its decision to prohibit use of mechanically separated product in baby, junior, and toddler foods. However, as currently worded it does not accurately reflect all of the determinations that the Department made in this area. In order to make this provision consistent with exclusions contained in the definitions and standards in the remaining sections of Part 319 of the regulations (9 CFR Part 319) and avoid future misunderstanding, the Department is amending the list of standardized products in § 319.6(d) of the regulations (9 CFR 319.6(d)), by adding the italicized language, to read as follows:

* * * ground beef, hamburger, fabricated steaks (§ 319.15 (a), (b), and (d)), barbecued meats (§ 319.80), roast beef—parboiled and steam roasted (§ 319.81), corned (cured) beef cuts §§ 319.100–319.103, certain cured pork products (§§ 319.104(a)–(e) and 319.106), tripe with milk (§ 319.308), lima beans with ham and similar products (§ 319.310), beef with gravy and gravy with beef (§ 319.313), and meat pies (§ 319.500).

(For similar reasons, the Department also is amending several of the definitions and standards for meat food products in which use of MS(S) is permitted. Those amendments are discussed below.)

As amended, § 319.6(d) of the regulations (9 CFR 319.6(d)) includes all of the standardized meat food products in which the Department determined, as part of its prior rulemaking, that use of mechanically separated product should be precluded. The Department still regards this set of products as inappropriate candidates for use of MS(S), with one possible exception: meat pies. In view of the interest expressed in the comments, the Department is hereby notifying the public that it is willing to reconsider the exclusion of MS(S) from meat pies upon a petition to amend §§ 319.6(d) and

319.500 of the regulations (9 CFR 319.6(d) and 319.500) because use of MS(S) does not appear to be inconsistent with the basic characteristics of this type of meat food product.

The Department expects that with the adoption of amendments to the regulations for mechanically separated product, production and use of this product will increase significantly. As this happens, the Department may well be confronted with additional questions about the appropriateness of using MS(S) in particular meat food products. Thus, for example, processors may wish to begin using MS(S) in meat food products that are not now included within a specific regulatory definition and standard, but that are similar to meat food products that are already covered by such regulations. These products may differ only in the species of livestock products used as ingredients the relative proportions of livestock products and other ingredients used, or the inclusion of additional ingredients to produce a distinctive flavor or style of product. The Department intends to handle such questions on a product-by-product basis consistent with the principles set forth above and, to the extent appropriate, amend Part 319 of the regulations (9 CFR Part 319) to reflect its determinations. One such question already is before it. The Department has been petitioned regarding regulation of the composition of ground pork, a meat food product that is not now covered by a specific regulatory definition and standard. The Department regards this product as analogous to ground beef, which is covered by a regulatory definition and standard (9 CFR 319.15(a)), with the only difference being the species of livestock from which the product is made. Therefore, it plans to propose amendments to the regulations that would establish requirements for ground pork that are comparable to the existing requirements for chopped or ground beef and thus would not include MS(S) among the ingredients permitted in ground pork for the same reasons that its use is not permitted in chopped or ground beef.

4. Finished Product Definitions and Standards

Adoption of amendments to the regulations for mechanically separated product necessitates only one change in the definitions and standards of identity or composition for finished meat food products in Part 319 of the regulations (9 CFR Part 319): Replacing the name "Mechanically Processed (Species) Product" with "Mechanically Separated (Species)" in each of the regulations

which states that "MP(S)P" may be used as an ingredient (9 CFR 319.15(c), 319.104(f), 319.105(b)(10), 319.141-319.144, 319.145(a)(1)-(3), 319.180(a)-(c), 319.182, 319.260, 319.261, 319.280, 319.281(a)(1), 319.300-319.302, 319.303(b)(9), 319.304-319.307, 319.311, 319.312, 319.600(a) and (b), 319.760(a), and 319.762). However, in view of its proposal to establish a category of product for processing to be used as an ingredient in meat food products with regulatory limits on their total fat content, the Department proposed an additional change in the definitions and standards for four meat food products in which use of mechanically separated product is permitted: replacing the 50 percent maximum on trimmable fat in the definitions and standards for fresh pork sausage (9 CFR 319.141), breakfast sausage (9 CFR 319.143), whole hog sausage (9 CFR 319.144), and smoked sausage (the smoked version of fresh pork sausage) (9 CFR 319.160), with a 50 percent maximum limit on the analytical fat content of the finished product. 46 FR 39274, 39289-90. The Department has concluded that the proposed amendments should be adopted so that product for processing may be used as an ingredient in these meat food products. The Department also has concluded that certain of the other definitions and standards (9 CFR 319.140, 319.145(a)(3), 319.281, and 319.305) should be amended to clarify that use of MS(S) is permitted.

Two comments addressed the proposal to replace the limit on trimmable fat in four definitions and standards with a limit on the fat content of the finished meat food products that they cover. Both of these comments were submitted by industry members and both supported the proposed amendments, with one commenter stating that fat analyses are preferable to the obsolete trim method as an indication of fat content.

As the Department noted in the proposal, the definitions and standard for fresh pork sausage, breakfast sausage, whole hog sausage, and smoked pork sausage currently state that they may not be made with any lot of product which, in the aggregate, contains more than 50 percent trimmable fat (i.e., fat that can be removed by thorough, practicable trimming and sorting). These controls operate on ingoing ingredients, and not the total fat content of finished products; and they require the visual evaluation of solid pieces of meat, and thus obviously cannot be applied to the finely comminuted product produced by mechanical deboning. Therefore, they do

not meet the Department's criteria for meat food products in which product for processing can be used. Those criteria are met once the regulations are amended by replacing the 50 percent trimmable fat limit with a 50 percent maximum on the analytical fat content of the finished product. The Department has concluded that the level in the amended regulations is appropriate for a finished product made with product containing no more than 50 percent trimmable fat in the aggregate of the ingoing ingredients.

The Department also has decided to amend certain other definitions and standards to clarify that MS(S) may be used as an ingredient in the meat food products they cover. As was just noted in the discussion of limitations on the use of MS(S) (9 CFR 319.6(d)), in 1978 the Department amended various definitions and standards that restrict the livestock products permitted as ingredients by adding language to allow use of mechanically separated product. These changes included amendments that specifically allow use of mechanically separated product in each particular type of standardized sausage product covered by the regulations. (References to use of mechanically separated product were added to §§ 319.141-319.145, 319.180, 319.182, and 319.281 of the regulations (9 CFR 319.141-319.145, 319.180, 319.182, and 319.281). No reference was needed in § 319.160 and § 319.181 of the regulations (9 CFR 319.160 and 319.181), which cover distinctive versions of sausage products that are also subject to the provisions of §§ 319.141 and 319.180 of the regulations (9 CFR 319.141 and 319.180), respectively. The intended effect of those changes was to permit use of mechanically separated product in various standardized sausage products, whether or not they are subject to the definitions and standards for particular types of sausage products. This intention may not be clear, however, because use of mechanically separated product is not referred to in § 319.140, the regulations that covers sausage generally (9 CFR 319.140). Therefore, to avoid possible misinterpretation in the future, the Department is clarifying the regulations by adding the following sentence to the end of § 319.140 (9 CFR 319.140):

Sausage may contain Mechanically Separated (Species) used in accordance with § 319.6.

The Department is amending §§ 319.145(a)(3), 319.281, and 319.305 of the regulations (9 CFR 319.145(a)(3), 319.281, and 319.305), the definitions and standards for certain Italian sausage

products, bockwurst, and tamales, respectively, for a similar reason. Each of these regulations covers more than one distinctive version of a type of meat food product. Each was amended in 1978 to provide that mechanically separated product may be used as an ingredient. The Department intended those amendments to result in mechanically separated product being permitted as an ingredient in each of the versions of the meat food products covered by these regulations. In order to clarify this intention, it is amending §§ 319.145(a)(3), 319.281(a)(1), and 319.305 of the regulations (9 CFR 319.145(a)(3), 319.281(a)(1), and 319.305) by moving the second sentence, referring to use of mechanically separated product, to the end of the provision.

5. Labeling

(a) The product.

In 1978 the Department did not see a need for special requirements for the labeling of mechanically separated product itself. With one category of standardized product subject to a unitary use limitation, no particular compliance problems were presented: mechanically separated product either could or could not be used as an ingredient in a particular meat food product; and if its use was permitted, it could constitute no more than 20 percent of the livestock and poultry product portion. Because the proposed amendments to the regulations would have changed this situation by establishing two categories of product, one of which could be used as an ingredient in more meat food products than the other and, at least potentially, at higher levels, the Department proposed the following labeling requirements to assure compliance with the amended use limitations: First, on the label of any mechanically separated product, the name of the product must be followed immediately by the phrase "for processing" unless the establishment is representing that the product contains not less than 14 percent protein and not more than 30 percent fat. Second, such product shall be deemed to have a calcium content of 0.75 percent unless the establishment represents that it has a different calcium content by qualifying the product's name with a phrase to this effect. 46 FR 39274, 39290. The Department has decided that the first of these proposed requirements is necessary in view of the adoption of amended regulations establishing a category of product for processing to be used as an ingredient only in meat food products with regulatory limits on their

total fat content. Therefore, it is amending the regulations to incorporate this requirement (9 CFR 317.2(j)(13)(i)). The Department has decided to withdraw the second of these proposed requirements as unnecessary in view of the withdrawal of the portion of the proposal that would have permitted usage levels of mechanically separated product meeting fat and protein content requirements to increase above 20 percent of the livestock and poultry product portion.

Three comments from industry addressed the proposal to establish special labeling requirements for mechanically separated product itself. While these commenters objected to the imposition of fat and protein content requirements on any category of mechanically separated product and, hence, to distinctions in use limitations based on the proposed two category approach, the concern here was that if the Department adopted this approach, the regulations make it clear that the phrase "for processing" is required only on the label of the mechanically separated product itself and not in the ingredient statements on finished meat food product labels.

The Department notes that the provision of the regulations incorporating this requirement (9 CFR 317.2(j)(13)(i)) specifically states that it applies to "the label of any 'Mechanically Separated (Species)' described in § 319.5(a)" of the regulations, not to the labels of meat food products in which MS(S) is used as an ingredient (compare 9 CFR 317.2(j)(13)(ii)). As this provision also indicates, § 319.5(a) of the regulations (9 CFR 319.5(a)) defines this product by the name "Mechanically Separated (Species)"; and, in accordance with § 317.2(c) (1) and (2) and (f)(2) of the regulations (9 CFR 317.2(c) (1) and (2) and (f)(2)), it is the name specified in the product standard that must be shown in the list of ingredients on the labels of meat food products, as further discussed below.

(b)-(d) Finished meat food products.

Ingredient Statement Listing

The Department continues to believe that mechanically separated product cannot be regarded as falling within the category of food traditionally defined as "meat" and that it should be defined as a distinctive, standardized ingredient. Therefore, it did not propose changing the requirement that the product must be declared, by the name specified in its definition and standard, in the ingredient statements of meat food products in which it is used. See *CNI v. Butz*, supra; 43 FR 26416, 26420-21; 46 FR

39274, 39283, 39290-91; 9 CFR 317.2(c) (1) and (2) and (f)(1). However, because the general labeling regulations already require a separate declaration of mechanically separated product (9 CFR 317.2(c) (1) and (2) and (f)(1)), repeating this requirement in the product-specific regulation (9 CFR 317.2(j)(13)) is unnecessary. Consequently, the Department proposed to delete the redundant reference to ingredient statement declarations in § 317.2(j)(13) of the regulations (9 CFR 317.2(j)(13)). 46 FR 39274, 39290-91. The Department has determined that this proposed amendment should be adopted.

No comments addressed this proposed amendment, but 141 comments addressed the ingredient statement requirement itself. The majority of these comments were submitted by industry-related individuals and groups. Many individuals also commented on this requirement, as did several State government officials and agencies.

Most of these commenters either accepted or affirmatively supported the requirement that mechanically separated product must be listed, by name, in the ingredient statements of meat food products in which it is used. Among the reasons given for their position were that this is consistent with all of the major Federal food statutes, the recommendation of the Panel, and the decision in *CNI v. Butz*, supra, and/or with the way other ingredients are declared. A number of commenters disagreed, however. These commenters generally took the position that this product is meat and no further identification, designation, or explanation is needed on finished product labels except, according to some, information on calcium content (in certain situations) because any added calcium in such products is the distinguishing characteristic involved here. Some of them also argued that this requirement should be removed because mechanically separated product is fit for human consumption or is wholesome and nutritious, because this would help to assure consumer acceptance or overcome adverse publicity about the product, and/or because the poultry and fish industries do not have to make such declarations; and one commenter contended that this requirement will result in the need for a number of labels to reflect different orders of predominance. In addition, a few commenters suggested that the requirement need not be applied where mechanically separated product is used at the 20 percent level because the calcium content is not nutritionally significant at this level. And a few took the position that the requirement need

not be applied to whole hog sausage labels because it is only natural that mechanically separated product flow right along with the rest of the carcass and/or the product name indicates all primal cuts are deboned and this should include mechanically separated product.

As is indicated above in the discussion of the product definition and standard (9 CFR 319.5), MS(S) does not consist solely of muscle tissue; it also contains bone, including bone marrow. The Department has determined material differences in composition and consistency place MS(S) outside the scope of the product defined by regulation as "meat" (9 CFR 301.2(tt)) and that its characteristics are such that it should be defined as a distinctive, standardized product. Therefore, this product must be declared on finished product labels by the name specified in its definition and standard. It is this distinctive character and separate regulatory standard that are the basis for the ingredient declaration requirement, and not the product's wholesomeness or fitness for consumption or the level or particular meat food product in which it is included as an ingredient. Furthermore, any concerns about consumer acceptance of this product, or about other products as to which the Department has not made such determinations, cannot be addressed by disregarding the Department's obligations to assure that the labels of meat food products containing MS(S) apprise the public of its presence. See 21 U.S.C. 601(n) (7) and (9) and 607(b); 9 CFR 317.2(c) (1) and (2) and (f)(1).

Supplementary Labeling Information

The Department proposed the following changes in the requirements for labeling in addition to a separate listing of MS(S) in ingredient statements: (1) the requirement that the names of all finished meat food products containing mechanically separated product must be qualified to indicate its presence would be deleted; however the need to retain the requirement for such a qualifier in particular situations would be considered on the basis of information submitted in the rulemaking. (2) The requirement that the names of all finished meat food products containing mechanically separated product must be qualified to indicate their powdered bone content would be replaced with a requirement that their labels declare calcium whenever the amount so declared would be different than the amount that would be declared if a particular finished product contained only hand deboned ingredients; and

alternative options that would serve the needs of calcium-sensitive individuals would be considered on the basis of information submitted in the rulemaking 46 FR 39274, 29290-94. The Department has reviewed and reevaluated the supplementary labeling requirements in light of the comments on the proposal, the provisions of the amended regulations, its current labeling policies, information on the use of calcium-restricted diets in managing health problems, and the information accompanying the PCMA-AMI petition. It has concluded that the qualifying phrases required in 1978 are not necessary to prevent misbranding of finished products containing MS(S) when MS(S) is used in accordance with the amended regulations and that, by modifying the requirements, it can reduce their burden and avoid unwarranted and possibly derogatory implications about meat food products containing mechanically separated product while continuing to assure that such products are accurately and adequately labeled. Therefore, the Department is amending § 317.2(j)(13) of the regulations (9 CFR 317.2(j)(13)) as follows: (1) The requirement that finished product names must be qualified to indicate the presence of mechanically separated product is deleted. (2) The requirement that finished product names must be further qualified to indicate their maximum powdered bone content is replaced with a requirement that information must be provided on such products' calcium content where there is a meaningful increase in the total calcium content of a meat food product that would otherwise be acceptable in the diets of persons on calcium-restricted diets. (That is, the meat food product's calcium content must be stated whenever MS(S) contributes 20 mg or more of calcium to a serving of the product unless the amount so declared would not be different than the amount that would be declared if the product contained only hand deboned ingredients or unless the calcium content of the product would be 20 percent of the U.S. RDA or more per serving if it contained only hand deboned ingredients (9 CFR 317.2(j)(13)(ii)).)

Five hundred and fifty-two comments addressed issues bearing on requirements for supplementary labeling information (i.e., information in addition to a separate listing of mechanically separated product in the ingredient statement). These comments can be divided into two general groups: (1) Comments that favor eliminating requirements that the names of meat

food products containing mechanically separated product must be accompanied by qualifying phrases and/or replacing powdered bone content declarations with a calcium content declaration approach and (2) comments that oppose eliminating one or both of the qualifying phrases required by the 1978 regulations or eliminating information regarding the presence of bone on the label.

About 70 percent of the comments fall into the first group. The majority of these comments were submitted by individuals. This group also includes numerous comments from industry members and groups, as well as several from professionals and State government officials and agencies. A few of these commenters restricted their criticism to any requirement that the presence of mechanically separated product must be indicated other than in the ingredient statement or that powdered bone content must be declared. The remainder advocated the elimination of all requirements for qualifying phrases. The qualifying phrases required by the 1978 regulations were characterized as negative, disparaging, derogatory, unnecessary, inappropriate, and/or onerous by these commenters. These phrases were criticized as giving undue prominence to a single ingredient which is virtually indistinguishable from or very similar to meat and as confusing and misleading to consumers, with research conducted by Market Research Service and for the Gerber Products Company cited in support of this position.

Those specifically addressing the qualifying phrase indicating the presence of mechanically separated product generally took the position that the appropriate place for this information is in the ingredient statement. Some of them said that there is no legitimate reason for indicating its presence elsewhere and/or that eliminating this requirement would minimize negative attitudes. Finally, a few commenters stated that if the ingredient statement is to serve a useful purpose, it must be relied on as the place that consumers interested in knowing what is in products will look. These commenters expressed concern that the recent trend toward qualifying phrases minimizes the importance of the ingredient statement almost to the extent that consumers are discouraged from looking at it.

Those specifically addressing the powdered bone content declaration generally supported replacing it with a calcium content approach. Some of them said that this approach is a sufficient and acceptable means of informing

those for whom calcium may be a problem, that it would be more useful to consumers, and/or that unlike the powdered bone content declaration it would not confuse consumers and would avoid erroneous implications of inferiority or mistaken concerns about the presence of hard pieces of bone. And one said that if powdered bone labeling is required, the same reasoning would require "blood residue", "blood vessels", "nerves", etc., to be stated on the label.

The argument that without qualifying phrases, the economies and efficiencies available from mechanical deboning will not be passed through to consumers also was criticized in a comment which contended that the wide range of meat food products now offered at very different prices shows the marketplace has proved efficient in assigning premium prices to premium products and passing through economies to the consumer. In addition, a number of commenters attributed the low levels of production and use of mechanically separated product since 1978 to the qualifying phrase requirements. They contended that with this labeling, meat food products would be unmarketable or would be erroneously perceived as inferior or as decharacterized and/or that this labeling has resulted in the waste of a valuable food resource. This situation was contrasted with that of products containing ingredients made by mechanically deboning poultry; and eliminating these qualifying phrases was supported as putting the red meat industry in a comparable and competitive position with other industries using the mechanical deboning technology.

A majority of the comments in the first group also addressed the proposal to replace information on meat food products' powdered bone content with information on their calcium content and to consider alternative options for serving the needs of calcium-sensitive individuals. Almost all of these commenters supported a calcium content approach as the appropriate method for dealing with the issues involved. Several of these commenters endorsed requiring calcium content or nutrition labeling declarations generally or as proposed. However, most of them criticized specific aspects of the proposed provisions implementing the calcium content approach, most frequently for resulting in calcium content information being required on the labels of too many meat food products. Their recommendations varied, and in certain cases reflected confusion about when the proposal

would and would not require calcium content to be declared; but they tended to advocate restricting calcium content information to where the amount present either in the finished meat food product or the mechanically separated ingredient is significant or nutritionally significant (a situation that a few of them thought would occur only occasionally). Those who quantified the concept of significance most often suggested 10 percent of the U.S. Recommended Daily Allowance (U.S. RDA) or 10 percent of the Recommended Dietary Allowance (RDA) per serving as the minimum level or minimum difference below which a label declaration of calcium content should not be required. (Exceeding the average content of hand deboned meat, a contribution of 2 percent or 15 percent of the U.S. RDA, and use of mechanically separated product above the 20 percent level also were suggested as criteria for determining whether or not a label declaration of calcium content is required.) The 10 percent of the U.S. RDA per serving position was supported by some as being consistent with the level set in the nutrition labeling regulations of the Food and Drug Administration (FDA) (21 CFR 101.9(c)(7)(v)); and a few comments also cited a 1974 proposal for a threshold for nutrient claims in food advertising by the Federal Trade Commission (39 FR 39841; notice of proposed termination and availability of staff revisions, 45 FR 23705). According to several of these commenters, mechanically separated product is only a moderate source of calcium; therefore, labels should not imply that meat food products containing it are excellent sources when such claims are not allowed for other products unless they contain at least 10 percent of the U.S. RDA per serving. It also was contended that below a significant level, the information is not needed and requiring it will clutter labels and result in processors having to maintain numerous labels for a single product, when such information is not required on other meat food products with higher calcium contents; and removing the requirement below the 10 percent per serving level was advanced as a way of encouraging the development of technology capable of producing mechanically separated product with a lower calcium content.

In addition, exemptions from any calcium content declaration requirement were requested by a few commenters who felt such a requirement would create problems for those manufacturing meat food products containing other ingredients high in calcium. While the

basis for this concern is not entirely clear, these commenters apparently misunderstood the proposed labeling as tying the amount of calcium declared to the mechanically separated ingredient and, thus, implying a higher use level of MS(S) when other ingredients contribute calcium. Finally, a few commenters opposed requiring calcium content declarations as unnecessary regulation and in order to save industry and consumers money or because mechanically separated product has been determined to be safe and wholesome, and calcium is an essential nutrient in which the average diet is likely to be somewhat deficient.

As regards the alternative statement proposed for use where nutrition labeling information is not provided, a few commenters took the position that "A—— serving contains ——% of the U.S. RDA of calcium" would be sufficient and the words "of this product" are superfluous. Opposition to requiring full nutrition labeling also was expressed. Very little comment was received regarding the alternative approaches discussed in the proposal. Two commenters supported restricting supplementary labeling information to a parenthetical statement in the ingredient statement of the fact that mechanically separated product is a calcium-containing ingredient. A few commenters specifically opposed such an approach, saying that it would be undesirable because mechanically separated product contains nutrients other than calcium or that information should be presented on finished meat food product content; and one said that it would be confusing to put nutrition information in ingredient statements. In addition, a few commenters specifically supported an information program to meet the needs of those on calcium-restricted diets as a supplement to labeling information. No additional information was submitted on the nature and treatment of the population segment for whom mechanically separated product's calcium content may pose a problem other than a statement by one commenter that recent statistics indicate less than 1 percent of our population must limit calcium intake.

About 30 percent of the comments addressing supplementary labeling information fall into the second group—opposition to the elimination of one or both of the qualifying phrases required by the 1978 regulations or to not providing information regarding the presence of bone on the label. Most of these comments were submitted by individuals. This group also includes comments from a public interest

organization and several professionals and State government officials or agencies. The basic position taken by most of these commenters was that the 1978 regulations should not be changed to provide less, or less prominent, information to consumers. Those few who did advocate changes made suggestions for additional labeling information, including declaration of the powdered bone content in the ingredient statement, the parts of the animal included in the product, and the amounts of calcium, fluoride, strontium 90, fat, and/or cholesterol.

Some of these commenters regarded the proposal as designed to serve the needs or convenience of industry rather than consumers and as making it more difficult for them to avoid a product that they believe should not be marketed, that they regard as unsafe, and/or that they do not want to purchase. Frequently they focused their remarks either on where information regarding the presence of mechanically separated product should appear or on the type of information that should be provided regarding bone content.

Those commenters specifically addressing the qualifying phrase indicating the presence of mechanically separated product favored this requirement because consumers have a right to know that mechanically separated product has been used or because this phrase clearly informs consumers of what they are buying. Providing this information solely in the ingredient statement was criticized as requiring the consumer to search for what actually is used and burying the information in fine print that is not normally noticed by consumers. One commenter who identified herself as someone who should avoid calcium objected to not having a prominent declaration of mechanically separated product. In addition, one commenter described the proposal to delete this requirement as applying an inventive regulatory standard which completely contradicts the Department's longstanding policy governing the substitution of a different or unusual product for a portion of the meat block. According to this commenter, not requiring specific nomenclature changes or qualifiers when a portion of the meat block is removed and an unexpected product is added also results in deliberate deception of the consumer, conflicts with the order in *CNI v. Butz* by ignoring the finding that a product in which mechanically separated product is substituted could not carry the conventional product name, and constitutes adulteration in contravention

of the Federal Meat Inspection Act (21 U.S.C. 601(m)(8)) because quality and value dilution would be concealed, especially where products contain more than insignificant amounts of mechanically separated product. The last of these conclusions was based on the argument that (1) mechanically separated product routinely contains a large amount of connective tissue, which lacks the essential amino acid tryptophan, and with use at up to the 100 percent level, products could be expected to be seriously deficient in tryptophan; (2) mechanically separated product has up to 60 times more lead, fluoride, cadmium, and other elements of questionable safety than meat and a product with "less" of these elements is preferable to one with "more"; and (3) products containing mechanically separated product are less expensive to produce, yet without nomenclature qualifiers, the likelihood is great that consumers could not distinguish between products with and without this ingredient and could thus be overcharged. This commenter's remarks regarding use in more than insignificant amounts and at up to the 100 percent level and another commenter's view that presence should most definitely be noted next to the finished product name if mechanically separated product is contained in a dominant amount (e.g., 51 percent) where the only submissions which suggested a basis for retaining this requirement for particular, but not all, uses of mechanically separated product. See 46 FR 39274, 39292.

Those commenters specifically addressing bone content labeling generally asserted that consumers have a right to know what is in the products they buy, including information on powdered bone content. Replacing this information with a calcium content declaration was criticized as disguising the bone content and as deceptive because bone contains other substances (e.g., fluoride, lead), calcium is regarded as a valuable nutrient, or calcium from mechanically separated product should not be grouped with calcium from sources such as milk solids. A few of these commenters accepted the calcium content approach so long as information on the amount or the presence of bone continues to be provided (e.g., by a declaration that the calcium is "from bone"); and some of those commenters regarded the bone content declaration as indicating a potential hazard to health. In addition, one commenter opposed the proposal as dangerous for calcium hyperabsorbers and as resulting in a potentially more serious problem for gout sufferers and other hyperuricemic

individuals. According to this commenter, in every likelihood, calcium hyperabsorbers who have already chosen a particular brand of products, and who are aware of the calcium content of those products, will not detect a new calcium declaration within the nutrition label or added in a separate place because most consumers do not reread ingredient or nutrition labels once they have become comfortable with a particular brand; so health problems could develop. This commenter also asserted that the proposal does not provide gout sufferers and other hyperuricemic individuals with the information they need because calcium is not the same as bone, bone brings bone marrow to finished products, bone marrow contains nucleic acid, and gout sufferers and other hyperuricemic persons must strictly limit consumption of nucleic acids; and contended that the Department is eliminating this important health protection before it is crystal clear that these people would not be at risk from the consumption of mechanically separated product, despite the admonition of the Court in *CNI v. Butz*.

The diversity of views expressed in these comments illustrates that, as the Department observed in publishing the proposal, the resolution of questions regarding the need for supplementary labeling information and the form any such information should take was controversial in 1978 and continues to be so today. Decisions in this area require difficult factual and policy determinations in which the Department must exercise its judgment, based on its accumulated experience, about the appropriate role of such information, if any, in preventing misbranding of products, as defined in the FMIA (21 U.S.C. 601(n)). 46 FR 39274, 39290-91. Requiring supplementary labeling information is one of a number of regulatory tools that the Department may utilize to achieve this goal.

In reaching conclusions about whether this regulatory tool should be used here and if so, how, the Department has carefully reviewed the comments and the information currently available in the context of the other regulatory controls it has imposed to prevent the use of mechanically separated product from resulting in misbranding as well as adulteration. 21 U.S.C. 601 (m) and (n). Thus, the Department has, among other things, utilized its authority to prescribe definitions and standards of identity or composition (21 U.S.C. 607(c)) to establish requirements for the processing and characteristics of MS(S)

(9 CFR 319.5) and for its use as an ingredient (9 CFR Part 319); and it has established requirements for the handling of MS(S) and the materials from which it may be made (9 CFR 318.18). These requirements not only assure that meat food products in which MS(S) is used as up to 20 percent of the livestock and poultry product portion are wholesome and safe, they also protect the quality (including the nutritional quality) and expected characteristics of such products. And, in particular, they reflect determinations that it is appropriate to include mechanically separated product among the livestock ingredients permitted in certain meat food products already subject to regulatory definitions and standards. 21 U.S.C. 601(m)(8) and (n)(2), (7), and (9). The Department also has required that the labels of all meat food products in which MS(S) is an ingredient bear the name of the species of the product used, in accordance with the definitions and standards for MS(S) and various finished meat food products and other regulatory requirements (9 CFR 317.2(c) (1) and (2) and (f)(1), 319.5(a), and Part 319). 21 U.S.C. 601(n) (7) and (9).

With these regulatory controls in place, the issue in this rulemaking is whether the Department should continue to require that the labels of meat food products containing mechanically separated product as 20 percent or less of the livestock and poultry product portion bear two qualifying phrases, or require alternative supplementary information, in order to assure that their labels are not otherwise misleading. 21 U.S.C. 601(n) (1) and (12). This issue is narrower in scope than many commenters suggested. For example, the issue here is not the consumer's right to know that mechanically separated product has been used in formulating a meat food product. The ingredient statement already provides that information. Moreover, the Department does not agree that listing MS(S) in the ingredient statement fails clearly to inform consumers of what they are buying. In fact, this listing includes such information in the one place that is specifically and explicitly designated for this purpose. The ingredient statement is the very place consumers should look, not ignore, if they are interested in the contents of the foods they purchase, in seeking out or avoiding any particular ingredients, or in distinguishing between brands of meat food products on the basis of their ingredient contents. Thus, the Department is concerned by commenters who indicate that they may

not be relying on ingredient statements for this purpose.

The issue in this rulemaking also is not the need for supplementary labeling information to apprise consumers that the formulations of meat food products they are accustomed to buying has changed. Such changes are reflected by modifications in the ingredient statement (and sometimes in other label information (e.g., nutrition labeling) that is affected). Thus, for example, if a manufacturer of chili con carne (9 CFR 319.300) chooses to replace up to 25 percent of the skeletal muscle trimmings it has been using with head, cheek, and/or heart meat, the change will be reflected by including head, cheek, and/or heart meat in the ingredient statement, as will a decision to include nonfat dry milk as up to 8 percent of the product. Because use of these new ingredients is consistent with the definition and standard for the product, its name will stay the same. However, where a manufacturer chooses to alter the basic identity of the product significantly by including beans and reducing the livestock product portion commensurately, the result will be a different meat food product with its own name—chili con carne with beans (9 CFR 319.301).

As manufacturers may modify the formulations of their products over time, particularly the formulations of products that have not been standardized, those interested in evaluating the contents of processed meat food products (e.g., in order to make interbrand value comparisons or to avoid or restrict consumption of particular ingredients) should consult ingredient statement information on a continuing basis, as opposed to relying solely on the fact that they have purchased a brand before. The legitimate concern of persons with health problems which involve dietary management is that they be able to determine when formulations are changed in ways that affect the acceptability of meat food products in their diets. The Department's requirements assure that the information necessary to make such determination is provided when mechanically separated product is used as an ingredient.

The ability to make such determinations also was the focus of concern in *CNI v. Butz*, *supra*. Noting that the question of misbranding under section 1(n)(1) of the FMIA (21 U.S.C. 601(n)(1)) had not been as fully argued, the Court said it appeared that the Department's 1976 interim regulation, which would have allowed the identical label to be used on a meat food product with and without mechanically

separated product, permitted misbranding since the calcium content of a product would be higher if mechanically separated product were used; and this could prove especially harmful to persons on calcium-restricted diets. (The Court used the possibility that "all beef franks" could contain mechanically separated product to illustrate the potential it saw for misleading the public. The Department agrees that such a characterization could be misleading in this instance and in others. Therefore, it does not permit cooked sausages, including franks, to be labeled with terms that indicate they do not contain nonmeat ingredients or are prepared only from meat (9 CFR 319.180(f)).

Furthermore, the Department does not agree that its proposal contradicts a longstanding policy under which the "meat block" of meat food products is basically immutable unless product names are changed or accompanied by qualifying phrases. In actuality, the "meat block" is the portion of a meat food product that consists of livestock, or livestock and poultry, products; and the make-up of this portion can vary greatly from meat food product to meat food product and also from brand to brand of a given meat food product. In addition to skeletal muscle, it may include other meat ingredients (e.g., muscle found in the tongue or heart) (9 CFR 301.2(t)), meat byproducts (e.g., tripe, spleen) (9 CFR 301.2(u)), poultry meat or poultry (9 CFR 381.118), and/or poultry byproducts (9 CFR 381.1(c)). The degree of variation in the types, amounts, and proportions of these products depends primarily on the extent to which the Department has restricted meat food product formulations in order to prevent misbranding and adulteration and on the formulation decisions of individual manufacturers.

For example, the Department has established a definition and standard for liver sausage (9 CFR 319.182) that permits the use of a broad range of livestock products—such as cured pork, beef, and veal; beef and pork byproducts; mechanically separated product; pork skin; and pork fat—but only in addition to a minimum liver content requirement of 30 percent. The individual manufacturer determines which of these optional ingredients to use and in what proportions, as well as whether to include only the minimum required amount of liver or more. As neither the presence nor the amount of any of the optional ingredients can be expected (and mechanically separated product cannot replace the minimum

liver content), inclusion of MS(S) in the formulation would not substitute for any particular ingredient. In this rulemaking the Department has asked why, when MS(S) is used as one of the livestock products, its presence should be noted in a qualifying phrase on the label of this meat food product, when the use of a broad range of other livestock products does not result in such a requirement. Other meat food products present similar situations, including the potential for even greater variability in the types and amount of livestock and poultry ingredients used in formulating nonstandardized meat food products—particularly in the proportion that is "meat"—which are marketed under the same name and without qualifying phrases to indicate the presence of certain livestock products (e.g., byproducts). Moreover, inclusion of MS(S) in the formulations of these meat food products could, among other things, result in an increase in the size of the livestock and poultry product portion, or in a partial replacement of nonlivestock ingredients such as chicken or cereal.

These examples are not cited to deny the appropriateness of ever requiring that the names of meat food products be changed or accompanied by qualifying phrases when certain ingredients are used or are used at certain levels. Instead, the point is that the Department's approach to this question has been to consider the facts of each situation and make its determination in light of the information available and its contemporary labeling policies. The issue frequently arises in the context of a proceeding to establish or amend a standard of identity or composition when, in addition to determining whether the inclusion of different amounts of various ingredients is appropriate at all in a particular type of meat food product, the Department considers whether any of the possible ingredient combinations affect product identity sufficiently to result in distinctive versions of that type of product.

Thus, in the case of cooked sausages such as hotdogs and bologna, the Department has determined there are two distinctive versions possible—one in which different byproducts can make up the predominant portion of the livestock and poultry product portion and one in which they may not be used (compare 9 CFR 319.180(b) with 319.180(a)). The supplemental phrase "with byproducts" or "with variety meats" is required to distinguish these two versions (9 CFR 319.180(d)). Yet, as just indicated, the Department has never taken the position that the use of

byproducts *per se* automatically results in the need for a qualifying phrase, even where such use may mean that one brand of a meat food product has less meat than another brand of the same product and, therefore, is less expensive to produce. Moreover, the Department's decision that cooked sausages such as hotdogs and bologna can contain poultry meat as up to 15 percent of the total ingredients, excluding water, without any finished product name qualifier (9 CFR 319.180(a)), even though this change would result in a reduction in the proportion of livestock meat ingredients used, illustrates that the Department has not automatically required supplementary labeling whenever there is a departure from traditional formulations or the inclusion of ingredients in the "meat block" which differ from those that usually have been used.

As this discussion and the proposal indicate, in determining whether to delete the requirement that the names of all meat food products must be qualified to indicate the presence of mechanically separated product, the fundamental question is whether inclusion of mechanically separated product as an ingredient—regardless of the meat food product or usage level involved—always significantly alters the basic identity of the finished product. The Department has determined that such a finding is not warranted, even if, as the Administrator concluded in the prior rulemaking, mechanically separated product is regarded as unexpected and unique. 43 FR 26416, 26420. The mere fact that an ingredient is new means that its presence in at least some existing products may not be expected by at least some consumers. However, this does not mean that its inclusion always alter a meat food product's identity sufficiently that its presence always should be noted in a product name qualifier. Such a *per se* approach simply is not appropriate or even feasible in an era when advances in food technology regularly result in the modification of existing product formulations to include new forms of ingredients, or even totally new ingredients. The mechanical deboning technology has made possible the introduction of a new form of livestock product. The unique properties of this product distinguish it from the livestock product "meat" produced by traditional hand deboning techniques (9 CFR 301.2(t)); but the properties of different types of meat (e.g., "beef" vs. "veal", "beef" vs. "beef cheek") and various byproducts (e.g., "beef tripe" vs. "partially defatted beef fatty tissue") also distinguish other livestock products

from one another. The Department regards distinctive properties or newness as an inadequate basis for a conclusion that all finished product names should be qualified.

In addition, while mechanically separated product does not fall within the category of food traditionally defined as "meat", it does consist largely of muscle tissue and shares many of the characteristics of "meat" when manufactured and used in accordance with the regulatory requirements established by the Department. As discussed above, these requirements protect the wholesomeness, safety, and quality of meat food products containing MS(S) as one of the livestock product ingredients. Among other things, they assure that MS(S) has protein of high quality and that its powdered bone content affects neither the safety nor acceptability of finished products. They also reflect an evaluation of whether or not it is appropriate to allow use of MS(S) in meeting up to 20 percent of the livestock or livestock and/or poultry ingredient requirements—including meat requirements—established for various standardized meat food products.

In the context of these regulatory requirements, the Department has determined that the mere presence of MS(S) does not significantly alter the basic identity of meat food products, let alone make them inferior to all other, similar products in which MS(S) is not used. Members of the public who do not want to purchase meat food products with MS(S), or want to purchase them only at lower prices than other products, can do so on the basis of ingredient statement declarations. This enables them to exercise their preferences in the marketplace, as they do with respect to other ingredients. The Department does, of course, hope that such decisions are not based on misperceptions about the product. As a number of commenters remarked and as this and the Department's earlier rulemaking demonstrate, health and safety aspects of the use of mechanically separated product have been thoroughly reviewed and the Department will continue to evaluate new data as they become available. Therefore, the Department is concerned by comments which indicate that the results of this process either are not understood, not accepted, or simply ignored. For example, as the Panel reported in 1977, cadmium concentrates in the liver and kidneys, not skeletal tissue, and was not even found at an analytically detectable level in mechanically separated product. There is no evidence that selenium

concentrates in bone and the upper levels found in mechanically separated product were either lower than or similar to those reported for beef and pork. The amount of lead that might be added to the diet by mechanically separated product is difficult to measure (since the products that could be replaced have variable lead contents), but it would, in any event, be toxicologically insignificant. And the amount of fluoride (an essential nutrient) that could potentially be added to the daily diet of a teenager consuming mechanically separated product with a 90th percentile fluoride concentration would be less than half the amount that researchers have found in 6 ounces of a soft drink.

The Department noted in the proposal its concern that the additional declaration of mechanically separated product in a qualifying phrase might contribute to misperceptions about the characteristics and quality of finished meat food products. 46 FR 39274, 39291. A number of the comments confirmed the concern that consumers may draw unwarranted conclusions from the labeling required in 1978. In addition, in the consumer focus group sessions conducted by Market Research Services, some participants who were shown a simulated label for a chili product felt that it contained a fairly large amount of mechanically processed beef product (MPBP) and began to wonder what was wrong with MPBP that would require its being labeled in such large letters. A number of these participants felt that there must be something wrong with MPBP if the government requires this type of labeling; and more than half felt it was unnecessary to emphasize MPBP in a qualifying phrase if there is nothing wrong with it, but it should be emphasized if the product is not safe or nutritious or if it denotes an inferior finished product.

The proposal also raised the possibility of retaining the requirement for a qualifying phrase indicating the presence of mechanically separated product in particular situations if the comments provided a basis for concluding that certain uses of mechanically separated product do alter the basic identity of meat food products significantly. 46 FR 39274, 39292. Neither the comments nor the Department's own evaluation has provided a basis for such a requirement where MS(S) can constitute only 20 percent or less of the livestock and poultry product portion. In fact, retention of the 20 percent restriction assures that MS(S) will not be the major portion of any meat food

product. In addition, other information indicates that MS(S) is likely to be used at below this maximum level. In their survey of meat packers and processors who have commercially produced or experimented with mechanically separated pork or beef, Drs. Bullock and Ward found that recommended formulations with mechanically separated pork were in the 5 to 15 percent range and most using mechanically separated beef included it at the 10 to 15 percent level. Drs. Bullock and Ward concluded that the usage level would be 5 to 10 percent of the meat block in most processed products (although it might be as high as 100 percent in some products if this were permitted by the regulations). The comments also evidenced industry interest in using mechanically separated product in small or functional amounts for technical purposes (e.g., as a binder) in various meat food products. In other words, MS(S) usually will be a relatively minor livestock product ingredient. To give its presence more labeling prominence than other livestock products used in the formulation is a disproportionate emphasis on a single ingredient.

The Department's determination that the labels of meat food products are not misleading without this qualifying phrase deals only with the use of MS(S) in accordance with the amended regulations. In other words, the Department is not by its action agreeing with those commenters who took the position that additional, qualifying label information never is necessary or appropriate. Therefore, future reconsideration of the limitations on use of MS(S) will involve not only the appropriateness of permitting expanded use, but also whether such use should be accompanied by a qualifying phrase indicating the presence of MS(S). In a future inquiry of this type, the Department will be particularly interested in the implications of expanded use for meat food products that include a species designation as part of their names. The Department's regulations already require that "meat" and the names of particular kinds of meat (e.g., "beef", "lamb") not be used in such a manner as to be false or misleading (9 CFR 317.8(b)(2)). The public should be aware that the Department considers it to be misleading to use this type of terminology in the name of a meat food product which does not contain "meat" or the kind of meat indicated.

The Department also has determined that the labels of meat food products containing MS(S) are not misleading

without a qualifying phrase indicating their maximum powdered bone content. However, unless supplementary labeling information is provided where there is a meaningful increase in the total calcium content of meat food products that would otherwise be acceptable in the diets of persons on calcium-restricted diets, such persons could be misled. This supplementary labeling issue arises because the mechanical deboning technology lets some hard bone pass through the equipment along with the soft tissue and, consequently, MS(S) has a higher calcium content than the livestock products traditionally used as ingredients in meat food products. As already discussed, other regulations are designed to assure that meat food products containing MS(S) with the maximum amount of hard bone and accompanying calcium which could be present are wholesome and safe. In fact, a slight benefit might be expected to result from the presence of additional calcium, especially for persons whose customary intake of this essential nutrient falls below the Recommended Daily Allowance. However, intakes below that level may be required for a small group of Americans. These persons are likely to be under medical supervision that includes dietary management to restrict their consumption of calcium-containing foods. Therefore, the Department's concern here is that such persons could be misled if they are not informed about those increases in meat food products' calcium content which should be taken into account in planning their diets.

This concern distinguishes the second qualifying phrase from the other labeling required in 1978, which was designed with the general population in mind. In reevaluating the second qualifying phrase, the question with respect to the general population is restricted to a consideration of whether this labeling can have unintended consequences on how meat food products containing MS(S) are perceived and evaluated. To the extent that there may be such unintended consequences, the question becomes whether these effects can be avoided while continuing to be responsive to the needs of the limited segment of the population for which this supplementary information is intended. In other words, the Department's objective here is to assure that persons on calcium-restricted diets have adequate information while not misinforming the general population.

The method selected in 1978 to reach this objective was labeling information on the component of MS(S) which results in increased calcium content—

powdered bone—presented in a qualifying phrase stating the maximum amount of the component that the regulations permit MS(S) to contribute to the finished meat food product. By proposing to replace this declaration with a calcium content approach, the Department was not, as some commenters thought, attempting to disguise the bone content or ignore the other substances in bone. Instead it was proposing to replace an indirect method of informing persons on calcium-restricted diets—those for whom this information is intended—with label information that is more useful because it directly addresses the content question of concern to them.

By adopting the calcium content approach, the Department also is providing information that is more consistent with the other types of content information on food labels: ingredient content, nutrient content, and quantity of contents information. Powdered bone content falls into none of these categories. It is a physical component of an ingredient—MS(S). In no other instance has the Department gone beyond the individual ingredients in a food (including the ingredients in a food used as an ingredient in another food) and required that their physical components be declared. In addition, this is the only instance in which the Department has required a quantitative declaration that may consistently and significantly overstate the amount actually present. Furthermore, adoption of a calcium content approach does not, as one commenter alleged, eliminate important health protection for gout sufferers and other hyperuricemic individuals. As discussed above in connection with the limitations on use of MS(S) (9 CFR 319.6), the Department has concluded that the formulation of meat food products with mechanically separated product used in accordance with the regulations does not present an increased risk to these people. It also should be noted that the Department never intended the second qualifying phrase, which declares powdered or hard bone content, to be misused by these people, or anyone else, as a statement of bone marrow content; and the amended regulations will continue to provide adequate identification of mechanically separated product to enable these people to avoid the product if they so choose. See 43 FR 26416, 26419.

Finally, the Department has concluded that the calcium content approach is preferable because it will respond to the needs of calcium-sensitive individuals without having unwarranted, negative

effects on the general population's evaluation of meat food products containing MS(S). As the Department noted in the proposal, the second qualifying phrase required in 1978 may misinform the general population about the characteristics of such meat food products. 46 FR 39274, 39294. When Market Research Services asked focus group participants to record their initial reactions to frankfurter labeling which included a statement that the product "contains up to 0.51 percent powdered bone" (i.e., to write down what it told them about the product), many of the respondents commented on this declaration, frequently negatively, and some misread the figure as 51 percent of thought that powdered bone was a separately added ingredient. As reported by Market Research Services, even after a discussion of the labeling, many of the participants felt that bone was added to the frankfurter, rather than associated with the mechanically separated ingredient, and they did not associate bone content with calcium content. Some of the comments also indicate that a powdered bone content declaration might be misunderstood to mean that bones have been ground up and used as an ingredient in meat food products such as hotdogs or luncheon meats or might be misinterpreted as a warning. In promulgating this requirement, it was not the Department's intention to disparage unfairly meat food products made with mechanically separated product. 43 FR 26416, 26420. Because the amended regulation provides information which is more consistent with the other types of content information on food label and which is relevant and useful for both persons on calcium-restricted diets and the general population, it is less likely to confuse the public.

The remaining questions in this area involve the implementation of the calcium content approach: on which finished meat food product labels should supplementary information on calcium content be provided and how should such information be presented. The Department has concluded that the proposed provision basically incorporates the appropriate answers to these questions. However, after reviewing the comments and information on the use of calcium-restricted diets in managing health problems, the Department has decided that the proposed provision should be modified somewhat. Under the amended provision (9 CFR 317.2(j)(13)(ii)), the amount of calcium, expressed as a percentage of the U.S. Recommended Daily Allowance (U.S. RDA) in a

serving, must be stated on the label of a meat food product containing MS(S) whenever MS(S) contributes 20 mg or more of calcium to a serving unless the amount to be declared would not differ from the amount that would be declared if the meat food product contained only hand deboned ingredients or unless the calcium content of the meat food product would be 20 percent of the U.S. RDA or more per serving if the meat food product contained only hand deboned ingredients.

The Department agrees with those commenters who took the position that it is not necessary to declare calcium content on the labels of all meat food products containing MS(S) and that labels should not imply that such products are better sources of calcium than they actually are. The Department does not agree, however, with a number of the commenters' recommendations regarding the level below which a calcium content declaration should not be required. In particular, the Department disagrees with suggestions that 10 percent of the U.S. RDA per serving should be used as a cut-off because that is the level FDA employs in regulating claims that a food is a significant or superior source of a nutrient (21 CFR 101.9(c)(7)(v)). The focus of concern in this rulemaking is not the appropriate minimum amount that should be required before a food is promoted to the general population on the basis of its value as a nutrient source. In that situation, the concern is that the public not be misled into thinking a food makes a greater nutrient contribution than it actually does. Here the concern is quite different: making sure that a population segment with particular health problems is not misled into thinking a food makes a smaller calcium contribution than it actually does. Put another way, FDA's regulation is designed to prevent claims from being made in the absence of nutritional significance; the Department's regulation is designed to assure content information is not omitted when increases occur that should be taken into account in planning calcium-restricted diets. Thus, these commenters, like a number of those who opposed replacement of the powdered bone content declaration, failed to focus on the needs of the special audience for which this information is intended. They presented no evidence as to whether or not persons on calcium-restricted diets would be misled if the labels of meat food products containing less than 10 percent of the U.S. RDA, or more than 10 percent of the U.S. RDA, of calcium in a

serving did not provide calcium content information.

The Department has concluded that persons on calcium-restricted diets could be misled if the labels of all of these meat food products were exempted from the calcium content declaration requirement. While the U.S. RDA for calcium is 1000 mg (1 g), persons on calcium-restricted diets are counselled to limit their calcium intakes to 600 or even 400 mg per day. (More severely restricted diets sometimes are used in hospital settings for people suffering from an acute condition or undergoing a diagnostic procedure, but generally only for a few days.) Thus, for these individuals, 10 percent of the U.S. RDA—100 mg—is about 17 to 25 percent of their daily intake. The calcium contribution of foods providing less than this amount is relevant to them; in fact, persons on calcium-restricted diets rely primarily on foods providing less than 10 percent of the U.S. RDA per serving in planning their diets.

The Department also has concluded that providing information on the labels of meat food products containing less than 10 percent of the U.S. RDA in a serving will not mislead either persons on calcium-restricted diets or the general population into thinking that such products contain more calcium than they actually do so long as this information is presented in the form of a quantitative declaration. FDA's nutrition labeling regulations provide for the declaration of the amounts of nutrients for which U.S. RDA's have been established in 2 percent increments up to and including the 10 percent of U.S. RDA level, with nutrients present in amounts less than 2 percent indicated by a zero or by an asterisk statement which explains that less than 2 percent of the U.S. RDA is present. These nutrients frequently are declared at levels below 10 percent of the U.S. RDA as part of a nutrition labeling profile of the food (see 21 CFR 101.9(c)).

The Department regards nutrition labeling as the most appropriate place for the information required by this regulation. Therefore, the regulation requires that the calcium content declaration appear as part of any nutrition labeling that a meat food product bears. However, as many meat food products do not bear nutrition labeling and the Department continues to ascribe to its 1978 conclusion that the issue of when nutrition labeling should be required is broader than the subject of this rulemaking (43 FR 26416, 26421), the regulation provides for an alternative declaration: If a meat food product bears no nutrition labeling

information, the calcium content declaration will appear in immediate conjunction with the ingredients list as part of a prominent statement which includes the serving size (i.e., the quantity of food) used in determining the amount present; for example, "A 2 ounce serving contains 4% of the U.S. RDA of calcium". [The alternative statement in the proposed provision has been shortened by deletion of the words "in this product" in response to comments that they are superfluous; the Department agrees that the statement is adequate without these words.] This exception to the general rule that nutrient information should appear in the context of a nutrition labeling profile is similar to the exception that FDA permits for sodium content information (21 CFR 101.9(a)).

Because it presents the amount of calcium in a prescribed format, the alternative declaration should not imply that the labeled product is a better calcium source than it actually is. The Department agrees, however, that such implications would be a problem if the amount of calcium were not stated. This is a major reason why the Department is not adopting one of the options raised as an alternative in the proposal: a parenthetical declaration, in the ingredient statement, of the fact that mechanically separated product is a calcium-containing ingredient. 46 FR 39274, 39294. In addition, incorporating nutrient information into a single ingredient listing in the ingredient statement of a meat food product which may well include other calcium-containing ingredients is inconsistent with the way nutrient information generally is presented and could be confusing.

As proposed and adopted, the regulation references the procedures and rules for determining and expressing the amount of calcium that are used by FDA in its nutrition labeling program (21 CFR 101.9 (b)(1), (c)(7) (i) and (iv), and (e)). The Department has concluded that these portions of FDA's nutrition labeling requirements are appropriate for the meat food products covered by its regulations. Among other things, these FDA regulations establish the increment levels for expressing calcium content: 2 percent increments up to and including the 10 percent of the U.S. RDA level, 5 percent increments above 10 percent and up to and including the 50 percent of the U.S. RDA level, and 10 percent increments above the 50 percent of the U.S. RDA level (with 1 gram (1000 mg) of calcium being equal to 100 percent of the U.S. RDA) (21 CFR 101.9(c)(7)). The proposal relied on

these 2, 5, and 10 percent of the U.S. RDA increment levels to define the scope of exceptions to the calcium content declaration requirement: A label need not bear a statement of calcium content when the amount to be declared would not differ from the amount that would be declared if the meat food product were made solely with hand deboned ingredients. When such a meat food product contains up to 10 percent of the U.S. RDA, increments of 2 percent of the U.S. RDA—or 20 mg of calcium—mean that relatively small calcium increases will result in calcium content being stated; but when such a meat food product contains greater amounts of calcium, increments of 5 or 10 percent of the U.S. RDA mean that greater increases will be necessary before calcium content must be stated. 46 FR 39274, 39293.

The Department continues to regard this proposed exception to the calcium content declaration requirement as appropriate and, therefore, has incorporated it in the amended regulation. However, the Department has determined that two other, similar modifications of the requirement can and should be added to control the costs of the requirement while assuring that calcium content information is not omitted when there are meaningful increases in meat food products' calcium content that should be taken into account in planning calcium-restricted diets. Therefore, the amended regulations do not require a calcium content declaration where MS(S) contributes less than 20 mg of calcium to a serving of a meat food product or where the calcium content of a meat food product would be 20 percent of the U.S. RDA or more per serving if such product contained only hand deboned ingredients.

The Department expected that the use of 2 percent per serving as the minimum amount to be declared as a percentage of the U.S. RDA would mean that calcium content need not be stated where small amounts of mechanically separated product are used in a meat food product that otherwise contains almost no calcium. While in theory this expectation is correct, in practice relying on the 2 percent per serving increment level for this purpose could result in a great deal of uncertainty. Manufacturers of meat food products who use mechanically separated product in small amounts still would have to monitor the composition of all of the other ingredients they use to assure that they contain "almost no" calcium. Even slight variations in the calcium content of these other ingredients could make the

difference between whether or not a calcium content declaration is required. Moreover, as many ingredients contain low levels of calcium, calcium content declarations might well be required even where a very small amount of mechanically separated product is used. For example, if the other ingredients in a meat food product contributed 14 mg of calcium (1.4 percent of the U.S. RDA) to a serving, a declaration would be required if 1 gram of mechanically separated product with the maximum calcium content of 7.5 mg (0.75 percent of the U.S. RDA) were used; but if the other ingredients contributed 11 mg, it would not be.

To rectify these problems, the Department is limiting the requirement to situations in which MS(S) contributes 20 mg or more—i.e., 2 percent of the U.S. RDA or more—of calcium to a serving of a meat food product. FDA uses 2 percent of the U.S. RDA not only as the minimum measurable difference to be stated in nutrition labeling (21 CFR 101.9(c)(7)(i)), but also in determining whether a food contains a nutrient in a measurable amount or any reduction in the content of a nutrient in its imitation labeling regulation (21 CFR 101.3(e)(4)). The Department has determined that it is not necessary to require a calcium content declaration where the MS(S) used in a serving of a meat food product results in an increase of less than this amount of calcium.

Moreover, incorporation of this exemption will facilitate compliance with the regulation by enabling manufacturers of meat food products in which MS(S) is used at low levels to determine with certainty that a calcium content declaration is not required either solely on the basis of the amount of MS(S) used in their formulations or on the basis of that information plus information on the calcium content of the MS(S) ingredient. For example, the livestock (or livestock and poultry) product portion of a hotdog with a 56.8 gram—2 ounce—serving size is about 85 percent of the total meat food product, or 48.28 grams. If mechanically separated product were used as 5 percent of this portion, it would constitute 4.25 percent, or 2.414 grams, of the total product; and its maximum calcium contribution (7.5 mg per gram) would be 18.11 mg, which does not have to be declared. Finally, this modification may encourage the development of technology capable of producing MS(S) with a lower bone content since the lower the bone content, the greater the amount of MS(S) that can be used without making a 20 mg contribution to a meat food product's calcium content.

As indicated above, the Department also expected that where meat food products made solely with hand deboned ingredients contain substantial amounts of calcium, the use of 5 and 10 percent increment levels would mean that calcium content need not be declared if use of the mechanical deboning technology resulted in only a relatively minor increase in calcium content; and it noted that a further exemption from the calcium content declaration requirement should be considered where the calcium content of meat food products is high enough to make them inappropriate for persons on calcium-restricted diets even without the inclusion of ingredients made by mechanical deboning. 46 FR 39274, 39292-93. Here, as well, the Department has concluded that the proposal relied too heavily on the increment levels to accomplish its objective and that in practice this would result in too much uncertainty for meat food product manufacturers. For example, because pizza with sausage (9 CFR 319.600(b)) is made with cheese, it contains a substantial amount of calcium—about 25 percent of the U.S. RDA in a 6 ounce serving—without any calcium contribution from the sausage. In addition, cooked sausage can constitute as little as 12 percent and dry sausage as little as 10 percent of the total product. It is, therefore, unlikely that use of the mechanical deboning technology in formulating the sausage part of this product would result in a large enough increase in calcium content to trigger a calcium content declaration; but there could be marginal situations in which a declaration of 30 percent of the U.S. RDA per serving would be required under the proposed provision.

The Department has determined that this result is not necessary to prevent the labels of meat food products such as pizza with sausage from misleading persons on calcium-restricted diets. Because these products already are regarded as high calcium foods, their inclusion in low calcium diets is unlikely; so any potential increase in their calcium content would not affect calcium intakes of persons at risk. To assure that calcium content declarations are not required in such situations, the Department is exempting the labels of meat food products that would have a calcium content of 20 percent of the U.S. RDA or more per serving if they contained only hand deboned ingredients. As with the exemption included in the proposal, in determining whether or not calcium content must be stated, the meat food product in question must be compared with one

that contains no ingredients produced by mechanical deboning, thereby taking into account the potential calcium contribution of product produced by mechanically deboning poultry carcasses. The Department has concluded that it would be inappropriate to base these exemptions on comparisons with products containing other ingredients made by mechanical deboning because unexpected increases in the calcium content of meat food products results from use of the mechanical deboning technology.

In its amended form, the regulation takes into account the fact that the calcium contributed by MS(S) can vary widely across a broad range of meat food products with very different ingredients. It recognizes the diluting effect that can occur when MS(S) is mixed with other ingredients and does not require quantitative information on calcium content when there is not a meaningful increase in the calcium content of meat food products that would otherwise be acceptable for persons on calcium-restricted diets.

While this is the only requirement in the regulations that may necessitate chemical analyses of finished products made with ingredients manufactured by mechanical deboning (other requirements necessitating chemical analyses are controlled at the ingredient manufacturing level), the Department has determined that the costs of complying with this requirement are not unreasonable and should not discourage meat food product manufacturers from using MS(S). In accordance with the Regulatory Flexibility Act (Pub. L. 96-354), the Department has considered the impact of the regulatory changes on small entities and the possibility that alternative requirements may substantially accomplish its objectives while minimizing this impact. (The Department's analysis of these issues is included in its Regulatory Impact Analysis.)

As discussed above, the Department has determined that one of the options considered as an alternative to quantitative information—a parenthetical statement in the ingredient statement of the fact that MS(S) is a calcium-containing ingredient—should not be adopted. The Department also has determined that, on the basis of currently available information, it cannot conclude that the other option considered as an alternative—an informational campaign about the calcium-containing characteristic of mechanically separated product—will, by itself, substantially achieve the

objective of assuring that the labels of meat food products containing MS(S) do not mislead persons on calcium-restricted diets. The Department does believe, however, that such a program has an important role to play in meeting the needs of these persons. Therefore, it will work with and take steps to inform and educate health professionals involved in the treatment of this group.

Other Comments

In addition to the views summarized above in the discussion of the final rule, the Department received numerous comments that expressed general views about the use of mechanically separated product. Many commenters supported use of mechanically separated product as acceptable and/or advantageous from a health and safety perspective. The extensive review and evaluation of this product and the 1977 Panel report were said to show that mechanically separated product and its constituents and composition present no problems and that the product is comparable to meat. Government control of factors such as handling and sanitation also was cited as assuring a safe, wholesome, and nutritious product. Some commenters advocated use of mechanically separated product as an additional source of food or protein and/or for its contribution of needed additional amounts of other essential nutrients—calcium and iron. Use of mechanically separated product also was supported as consistent with the production of meat food products with sensory characteristics (e.g., taste, appearance, texture) comparable to or, sometimes, better than those now produced. Some of these commenters expressed concern that the public has been misinformed about the characteristics of mechanically separated product; for example, that people expect the product to contain chips or pieces of bone when this actually is more likely to be a problem with hand trimmed meat.

A number of other commenters opposed use of mechanically separated product or indicated their desire not to consume it based on health and safety and/or quality concerns. Damage to teeth, the problems of persons on calcium-restricted diets and gout sufferers, protecting children, the inferiority of the product to meat, and the belief that the product is impure, contains substances that may be hazardous, or adulterates were given as reasons for this position.

Use of mechanically separated product also was supported by many commenters as a way to increase

productivity, improve or optimize resource utilization, reduce the current waste or inefficient use (e.g., for rendering or animal feed) of materials suitable for mechanical deboning, and/or increase the utilization of lower quality cuts of meat. A number of economic benefits for various groups and the American public at large were predicted to result from the production of mechanically separated product and the consequent increases in carcass yields and food supplies. These included increases in employment, the return to animal producers on their investment, and competition in domestic and international markets; providing a new source of product for export and a means of reducing meat imports; and reducing the cost of producing meat food products and reducing or slowing the rise in the prices paid by consumers. Other commenters agreed that the cost of producing meat food products would or could decrease, but doubted that this would be reflected in lower prices for consumers (e.g., due to the cost of the deboning equipment).

Finally, a number of commenters addressed the Department's approach to the regulation of this product. The proposal was supported as decreasing overregulation and as making the regulatory treatment of product made by mechanically deboning livestock more consistent with that of similar products made by mechanically deboning poultry and fish. Differences in the regulatory treatment of these products were criticized as without foundation, discriminating against the red meat industry, and confusing to importing countries. Applying the same requirements to products made by mechanically deboning livestock and poultry carcasses was advocated, as was merging these products into a single classification. Consistency in the standards applied by different countries also was advocated, as was permitting meat food products for export to be formulated and labeled to meet the requirements of the countries to which they are being sent where these differ from the ones established by the Department.

As a number of these views also were expressed in comments relating to specific provisions of the regulations, they already have been discussed. Economic aspects of the regulations, as promulgated in 1978 and as amended herein, are discussed in greater detail in the Department's Regulatory Impact Analysis.

The Department agrees that it is important to take advantage of all safe and wholesome sources of food. This

final rule is designed to help achieve that goal while continuing to fulfill the Department's statutory responsibility to protect the public against adulterated and misbranded products. The final rule rests on rulemaking proceedings in which health and safety as well as quality aspects of the use of mechanically separated product have been thoroughly assessed. It incorporates regulatory requirements and restrictions that the Department has determined to be appropriate as a result of those proceedings. While various regulatory provisions have been considered during the proceedings, the Department's objectives have remained the same. At each stage of this process, the Department has had to exercise its judgment based on the information available at the time; and it has indicated that additional information may warrant further action regarding the regulation of this product.

As noted in the discussion of the final rule, this continues to be the case. Thus, for example, the Department continues to be willing to reexamine the maximum bone particle size limit on the basis of data substantiating that good manufacturing practice may result in somewhat larger bone particles which do not present safety or digestibility problems; and it expects that additional questions about the appropriateness of using MS(S) in particular meat food products will arise and be handled on a product-by-product basis. Similarly, the development of potential outlets for MS(S) in the export market may well raise questions in the future. While the Department understands the desire for consistency in the standards applied by different countries, it cannot anticipate the requirements that other countries may develop over time, nor assure that those requirements will be consistent with one another. Moreover, as each country's requirements reflect the law developed to meet the needs of its population, it is quite likely that such requirements will differ, at least to some extent. The Department generally regulates product prepared for export in the same manner as product prepared for domestic consumption, but it does permit deviations from United States requirements where such action is consistent with its statutory responsibilities.

Regulatory Impact Analysis

As indicated above, this action has been reviewed under USDA procedures established to implement Executive Order 12291. In compliance with section 2 of that order, the Department's review is reported in its Regulatory Impact

Analysis (RIA), which is available upon request and summarized herein.

The objectives of the RIA are as follows: First, to determine whether or not there is substantial information regarding the necessity and potential consequences of the regulatory changes. Second, to determine whether or not the potential benefits to society resulting from the regulatory changes outweigh the costs of such changes. Third, on the basis of an analysis of alternative ways of satisfying the objectives of the regulatory changes, to determine whether or not the amendments will tend to maximize the net benefits to society. The Department's analysis indicates that each of these questions should be answered in the affirmative.

The following outline describes the steps that the Department took in reaching these conclusions:

1. The objectives of the changes were set forth along with their justification. The causes of the problems which the amendments are designed to address and the methods by which they would correct these problems were analyzed.

2. Three alternatives were analyzed: the 1978 regulations, the amended regulations, and "no regulatory action" (i.e., rescinding the 1978 regulations).

3. In analyzing the changes and possible alternatives, the costs and benefits of the current regulations were compared with the potential costs and benefits that could result from changing these regulations. The direct and indirect costs to be borne both by consumers and various segments of industry were explored and compared with the direct and indirect benefits to such groups. Costs and benefits were quantified in monetary terms where possible and where this could not be done, they were described in detail. The RIA includes an explanation of the types of benefits anticipated and the mechanism by which the changes are expected to result in these benefits. In addition, it responds to comments submitted by the public on the Department's preliminary analysis of these issues.

The RIA also satisfies the analysis requirements of the Regulatory Flexibility Act (Pub. L. 96-354), which deals with the impact of regulations on small entities. The objective of this portion of the analysis is to consider the impact of the regulatory changes on small entities and the appropriateness of tailoring regulatory requirements to the sizes and types of businesses involved. The Department's analysis in this area indicates that the costs that small businesses entering the mechanically separated product market will face

under the amended regulations basically are the costs of entering any new market; and, thus, while such costs will be relatively greater for small than for large businesses, this is not the result of the regulations *per se*.

The PCMA-AMI attributed the limited production of mechanically separated product since 1978 to "unreasonably restrictive compositional requirements and misleading labeling requirements":

(1) Mechanically separated product must contain not less than 14 percent protein and not more than 30 percent fat.

(2) The labels of meat food products containing mechanically separated product must bear qualifying phrases indicating its presence and their maximum powdered bone content; and they must identify the product by the name "Mechanically Processed (Species) Product". In support of this position the petitioners submitted a report on a series of consumer focus group sessions and an analysis of the economic impacts of the 1978 regulations by Bullock and Ward. Bullock and Ward agreed that the 1978 regulations have had the unintended effect of making it uneconomical to use an efficiency-improving technology. They found these regulations to have a small impact on the costs of producing mechanically separated product, but a large impact on the potential supply. The economic costs of the 1978 regulations were attributed to the labeling requirements for products containing mechanically separated product and to the fat and protein content requirements for the product. Bullock and Ward concluded that requiring the meat food product label to contain information on calcium content would generate the same benefits as the 1978 regulations without the social costs associated with them. Bullock and Ward also concluded that the 20-percent restriction on the usage level of mechanically separated product does not appear to be generating social costs at the present time and will not likely restrict the total output of the product (although they recommended that this restriction be removed as without economic justification and in order to preclude development of potential new products that might be acceptable).

In view of these arguments and the information in the Bullock and Ward analysis, the Department analyzed the three alternatives set forth above (see steps 2 and 3). The following table and text summarizes the Department's conclusions regarding each of these alternatives. They are based on data for 1979.

ECONOMIC IMPACTS OF THE ALTERNATIVES ¹

Alternative	Economic benefits	Economic costs	Net economic benefits
In millions of dollars			
The 1978 Regulations...	0	(²)	
The Amended Regulations	495.0	³ 1.9	493.1
No Regulatory Action	495.0	0	495.0

¹ Estimates are based on projected levels of production of mechanically separated beef and mechanically separated pork. Lamb and calf carcasses and parts also can provide raw materials for mechanical deboning, but only in amounts that are very small in comparison with potential production from cattle and hog carcasses.

² Direct costs were not estimated due to the low levels of mechanically separated product produced since promulgation of the 1978 regulations. Indirect costs of \$495 million are equal to the projected economic benefits of the amended regulations.

³ These economic costs reflect estimates of the testing component of quality control costs. No attempt was made to estimate the aggregate costs relating to reporting or management of a quality control system and labeling due to lack of available data. These costs are not considered to be a major component of direct economic costs.

The 1978 Regulations

The regulations promulgated in 1978 generated indirect economic costs (such as foregoing market opportunities and productivity losses) that are equal to the economic value of the technology not realized because of the existence of these regulations. The Department estimate these costs to be about \$495 million. This estimate was obtained by multiplying an average retail price for meat by the amount of mechanically separated product likely to be produced and then subtracting out raw material and processing costs and profit. (Bullock and Ward did not include profit in their estimate and, therefore, estimated higher costs.) There are no substantial direct economic costs or benefits generated under these regulations as the levels of production of mechanically separated product have been so low.

The Amended Regulations

The economic benefits of the amended regulations are the benefits that will result from the production which is estimated to have been foregone because of the 1978 regulations. Therefore, the economic benefits of the amended regulations are the same as the indirect economic costs generated by the 1978 regulations: \$495 million.

Bullock and Ward estimated the economically feasible 1979 level of production at 351.7 million pounds without the finished product labeling and fat and protein content requirements described above. The Department has concluded that potential production under the amended regulations would have been the same as that estimated by Bullock and Ward because (1) the names of finished products containing MS(S) need not be accompanied by qualifying phrases and (2) retaining fat and protein content

requirements for MS(S) used in meat food products without regulatory limits on their total fat content will not constrain the potential supply of MS(S). (The Department also does not expect the 20 percent restriction on the amount of MS(S) that may be used to constrain the potential supply of MS(S). This is consistent with the findings of Bullock and Ward.)

Use of the mechanical deboning technology also is expected both to increase and decrease the value of carcasses. On the one hand, the value of a carcass would be increased as several pounds of MS(S) can be recovered that would otherwise have been sold for lower value uses. On the other hand, widespread use of the technology would increase the total supply of ingredients for making processed meat food products. This increased supply is expected to cause the prices of processed meat food products to fall. As their prices fall, it is expected that these products will capture part of the market for table cuts. As the demand for table cuts falls in response to lower prices for processed meat food products, prices for table cuts also should fall, resulting in a decrease in the value of carcasses. The net impact on the value of carcasses depends on the magnitude of these price movements. The effect of increased supplies could more than offset the increased value of carcasses and result in a net lowering of live animal prices and a lowering of net farm income.

In such a situation, processors would benefit from being able to use less expensive ingredients and consumers would benefit from lower retail prices. Livestock producers, however, would receive lower livestock prices and, therefore, income would be transferred from producers to processors and consumers. Consumers are expected to receive most of this transfer due to the competitive nature of the food processing industry. The Department estimated the income transfer at \$493 million, using the Bullock and Ward estimate of 1979 potential production. That would represent a 0.3 percent decrease in total farm revenue, based on the Department's estimate of farm revenue in 1979. This conclusion was challenged by a few of those commenting on the proposal, and a statement by Bullock and Ward was submitted which suggested that the negative impact on livestock prices and net farm income which they calculated would not be as great as estimated or could even disappear because there should be a price incentive to replace some imported beef with mechanically separated beef.

The Department agrees that MS(S) might replace some of the imported meat now used in various meat food products due to the substantially lower expected price of MS(S). No attempt has been made however, to predict the extent to which this will occur because the current levels of production of mechanically separated product are so low that the market has not been established to the point where a reasonable estimate can be made. (In their statement, Bullock and Ward said it does not seem unreasonable that perhaps as much as 10 percent of imported beef could be replaced by mechanically separated beef in processed products.) To the extent that production of MS(S) is offset by a decrease in imported meat, the increase in the supply of ingredients for use in processed meat food products would not be as great and, hence, the negative impact on livestock prices and net farm income would be less than estimated, or could even disappear, and would be replaced by a loss to foreign exporters in the form of decreased sales. Net economic gains would still result as processors benefit from using less expensive ingredients and consumers benefit from the savings passed on to them.

The direct economic costs under the amended regulations relate to compliance with the requirements that MS(S) be produced under a plant quality control system and that the labels of meat food products containing MS(S) declare its presence in their ingredient statements and, with exceptions, declare their calcium content. The Department has concluded that the costs of complying with these requirements are very small compared with the economic value of increased production and use of MS(S) and that they are not unreasonable and should not discourage production or use of MS(S) as an ingredient in meat food products. These conclusions are consistent with the finding by Bullock and Ward that the 1978 regulations have only a small impact on production costs and their assumption that the contents portion of meat food products labels will bear enough information to allow individuals who must restrict their calcium intake to avoid consuming too much mechanically separated product.

The Department estimated the aggregate yearly quality control testing costs for producing 351.7 million pounds of mechanically separated product to be \$1.9 million, or 0.38 percent of \$495 million, the estimated value of the product at this level of production. (These costs are somewhat lower than

the costs under 1978 regulations as a result of amendments to the quality control provision.) Reporting and administrative costs of plant quality control were not estimated due to the lack of data, but they are considered not to be a major component of direct economic costs. Moreover, institution of plant quality control should be accompanied by countervailing benefits: by providing controls and information that maximize the likelihood that product of consistent and uniform quality which complies with regulatory requirements will be manufactured at a predicted cost, quality control helps to minimize costs. Finally, the plant quality control required in the amended regulations may be integrated with other, voluntary plant quality control programs or with a total quality control system.

There also will be costs associated with changing the labels of meat food products in which MS(S) is used. As very few products currently are being formulated with mechanically separated product, these costs are not the result of amending the regulations. Moreover, the Department regards the costs of changing labels to include MS(S) in the ingredient statement as costs that are incurred whenever a manufacturer decides to modify its product formulation to include a different ingredient.

Finally, the Department evaluated the costs of requiring that calcium content be declared where there is a meaningful increase in the total calcium content of meat food products containing MS(S) which would otherwise be acceptable for persons on calcium-restricted diets. It is difficult to estimate these costs because the frequency with which meat food products' calcium content may have to be analyzed and the costs of such analyses will vary a great deal and because manufacturers will control these costs to some extent through their formulation decisions.

A number of private laboratories charge \$15 to \$25 to test for calcium content. (In-house testing costs are lower.) If such analyses were conducted once a month at an average cost of \$20 per test, the annual expenditure would be approximately \$240. However, in a number of instances, manufacturers should be able to determine the calcium content of meat food products, or determine that a calcium content declaration is not required, from information on the ingredients used. Manufacturers also can use this information in making their formulation decisions. In addition, the Bullock and Ward analysis of the levels at which

many manufacturers are likely to use mechanically separated product and the likely production of mechanically separated product with less than the maximum amount of calcium permitted mean that MS(S) probably will contribute less than 20 mg of calcium per serving to a number of meat food products in which it is used. Nor will additional costs be incurred where calcium content information already is provided as part of nutrition labeling.

The Department also does not regard the costs of incorporating calcium content information in meat food product labels that do not bear nutrition information as a major component of direct economic costs. The alternative statement included in the regulations can be included with the changes that manufacturers regularly make for marketing purposes or to reflect modifications in their formulations.

No Regulatory Action

The no regulatory action alternative (i.e., rescinding the 1978 regulations) would not be consistent with the Department's statutory responsibilities. If such action could be taken, the economic benefits of this alternative would be the same as those that are projected under the amended regulations because the amended regulatory requirements will not constrain the potential supply of MS(S) or the production or marketing of meat food products in which MS(S) is used. (This conclusion is consistent with the findings of Bullock and Ward regarding various regulatory requirements and the production of and demand for the product.) However, as the economic costs of no regulatory action would be somewhat less, net economic benefits would be somewhat greater.

Legal Memorandum Regarding USDA Authority to Promulgate This Rule

Pursuant to section 4(a) of Executive Order 12291, issued on February 17, 1981, the Office of the General Counsel of this Department has reviewed the above referenced rule and determined that its promulgation is clearly within the authority delegated by law to the Secretary and is consistent with the Congressional intent of the Federal Meat Inspection Act, as amended, 21 U.S.C. 601 *et seq.*

Under the Act, the Secretary is required to cause inspection of meat and meat food products and take other actions to assure that they are wholesome, not adulterated or misbranded, and properly marked, labeled and packaged. Section 21 of the Act, 21 U.S.C. 621, requires the Secretary

to appoint inspectors to examine meat and meat food products and sanitary conditions of establishments in which they are produced to assure that they are not adulterated. Section 21 also authorizes the Secretary to " * * * make such rules and regulations as are necessary for the efficient execution of the provisions of this Act * * *."

Section 7 of the Act, 21 U.S.C. 607, gives the Secretary authority to prescribe definitions and standards of identity or composition for articles subject to the Act whenever he determines such action is necessary for the protection of the public. Consistent with these provisions and the intent of Congress, as expressed in Section 2 of the Act, 21 U.S.C. 602, this rule aids in the economical expansion of the nation's food supply while protecting the health and welfare of the consuming public.

Final Rule

List of Subjects

9 CFR Part 317

Mechanically Separated (Species).
Food labeling.

9 CFR Part 318

Mechanically Separated (Species).
Preparation of products.

9 CFR Part 319

Mechanically Separated (Species).
Meat and meat food products, Standards of identity or composition, Quality control, Food labeling.

On the basis of the foregoing, the Federal meat inspection regulations (Parts 317, 318, and 319) are revised as follows:

1. The authority citation for Parts 317, 318, and 319 reads as follows:

Authority.—34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 594, 84 Stat. 91, 438; 21 U.S.C. 607, 621.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

2. Section 317.2(j)(13) (9 CFR 317.2(j)(13)) is revised to read as follows:

§ 317.2 Labels: definition; required features.

(j) * * *

(13)(i) On the label of any "Mechanically Separated (Species)" described in § 319.5(a) of this subchapter, the name of such product shall be followed immediately by the phrase "for processing" unless such product has a protein content of not less than 14 percent and a fat content of not more than 30 percent.

(ii) When any "Mechanically Separated (Species)" described in

§ 319.5 of this subchapter is used as an ingredient in the preparation of a meat food product and such "Mechanically Separated (Species)" contributes 20 mg or more of calcium to a serving of such meat food product, the label of such meat food product shall state the calcium content of such meat food product, determined and expressed as the percentage of the U.S. Recommended Daily Allowance (U.S. RDA) in a serving in accordance with 21 CFR 101.9(b)(1), (c)(7) (i) and (iv), and (e), as part of any nutrition information included on such label, or if such meat food product does not bear nutrition labeling information, as part of a prominent statement in immediate conjunction with the list of ingredients, as follows: "A ——— serving contains ———% of the U.S. RDA of calcium", with the blanks to be filled in, respectively, with the quantity of such product that constitutes a serving and the amount of calcium provided by such serving: *Provided*, That, calcium content need not be stated where (a) the percent of the U.S. RDA of calcium to be declared would not differ from the percent of the U.S. RDA that would be declared if the meat food product contained only hand deboned ingredients or (b) the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more if the meat food product contained only hand deboned ingredients.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

§ 318.18 [Amended]

3. Section 318.18 (9 CFR 318.18) is amended by replacing the words "Mechanically Processed (Species) Product" or into an imitation of such product" in the first sentence with the words "Mechanically Separated (Species)" and by replacing the words "Mechanically Processed (Species) Product" or an imitation of such product" in the second sentence with the words "Mechanically Separated (Species)".

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

4. Section 319.5(a) and (e) (1) and (2) (9 CFR 319.5 (a) and (e) (1) and (2)) are revised to read as follows:

§ 319.5 Mechanically Separated (Species).

(a) Mechanically Separated (Species) is any finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of

livestock carcasses and parts of carcasses and meeting the other provisions of this paragraph. Examples of such product are "Mechanically Separated Beef", "Mechanically Separated Veal", "Mechanically Separated Pork", and "Mechanically Separated Lamb". At least 98 percent of the bone particles present in such product shall have a maximum size no greater than 0.5 millimeter in their greatest dimension and there shall be no bone particles larger than 0.85 millimeter in their greatest dimension. The product resulting from the separating process shall not have a calcium content exceeding 0.75 percent, as a measure of a bone solids content of not more than 3 percent, and shall have a minimum PER of 2.5 (except as modified in paragraph (e)(1) of this section). Such product also shall have a protein content of not less than 14 percent and a fat content of not more than 30 percent, or it shall be deemed to be product for processing. Such product failing to meet the bone particle size, calcium, or PER requirements of this paragraph shall only be used in producing animal fats. Where such product meets the bone particle size, calcium, and PER requirements of this paragraph, it may also be used in the formulation of meat food products in accordance with § 319.6.

(e)(1) An essential amino acid content of at least 33 percent of the total amino acids presents in "Mechanically Separated (Species)" shall be accepted as evidence of compliance with the protein quality requirement set forth in paragraph (a) of this section. For purposes of this paragraph, essential amino acid content includes isoleucine, leucine, lysine, methionine, phenylalanine, threonine, and valine content, and the total amino acids present include isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine, tyrosine, arginine, histidine, alanine, aspartic acid, glutamic acid, glycine, proline, serine, and hydroxyproline content.

(2) A prerequisite for label approval for products consisting of or containing "Mechanically Separated (Species)" is that such "Mechanically Separated (Species)" shall have been produced by an establishment under an approved plant quality control system. The Administrator shall receive, evaluate, and approve requests for plant quality control in accordance with § 318.4(d)(1) and (2) and (e) of this subchapter. Such a plant quality control system shall provide the controls and information necessary to assure that the product will

meet the requirements described in § 319.5(a) and to enable establishment personnel and program employees to monitor the system for effectiveness. The system shall include a written description of the methods used by the establishment to maintain uniformity of the raw ingredients used in manufacturing product, to control the handling and processing of the raw ingredients and the finished product, and shall contain provisions for chemical analyses of the product and other procedures to determine and assure compliance with standards for the product. For purposes of this paragraph, a lot shall consist of the "Mechanically Separated (Species)" designated as such by the operator of the establishment or his or her agent from the product produced from a single species of livestock in no more than one continuous shift of up to 12 hours. All units of any lot must be available for inspection by program employees. Analysis of a sample of at least 1 pound from each lot to verify contents of fat, protein, and calcium in "Mechanically Separated (Species)" shall be performed by the operator of the establishment or his or her agent to assure that finished product will meet the requirements in § 319.5(a), except that such analyses with respect to fat, protein, and calcium content shall be required to be performed with respect to only one randomly selected lot of every five lots if the preceding ten analyses and all such analyses performed by the Department during the preceding ten analyses period establish compliance with the requirements of § 319.5(a), and that no analyses with respect to fat or protein content shall be required where the finished product is represented as product for processing. An analysis of a sample of at least 1 pound to verify essential amino acid content and/or protein efficiency ratio in "Mechanically Separated (Species)" shall be performed by the operator of the establishment or his or her agent at the rate of at least one per month during production to assure that finished product will meet the requirements of § 319.5(a), except that such analyses with respect to essential amino acid content and/or protein efficiency ratio shall be required to be performed only once every 6 months if the preceding three analyses and all such analyses performed by the Department during the preceding three analyses period establish compliance with the requirements of § 319.5(a). Finished product samples shall be analyzed in accordance with "Official Methods of Analysis of the Association of Official Analytical Chemists"

(AOAC), 13th ed., 1980, sections 24.005 (page 376), 24.006-24.008 (page 376), 24.027 (page 379), and 43.212-43.216 (page 774-75) and the "2nd Supplement to the 13th Edition" (J. AOAC, Vol. 64, No. 2, 1981), section 24.B01-24.B03 (pages 509-10), which are incorporated by reference, or if no AOAC method is available, in accordance with the "Chemistry Laboratory Guidebook," U.S. Department of Agriculture, Washington, D.C., sections 6.009-6.009F (pages 6-31 through 6-34) and 6.010-6.010D (pages 6-35 through 6-41). Alternative methods of analysis may be submitted to the Administrator to determine their acceptability based upon their accuracy, repeatability, reproducibility, and lowest level of reliable measurement, as demonstrated by at least 3 laboratories. (Copies of the AOAC methods may be obtained from: AOAC, 1111 N. 19th Street, Arlington, VA 22209. Copies of the Chemistry Laboratory Guidebook may be obtained from: Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. This incorporation by reference was approved by the Director of the Federal Register on December 30, 1981 and March 15, 1982. These materials are incorporated as they exist on the date of the approval. A notice of any change in the sections of the AOAC methods or the Chemistry Laboratory Guidebook cited herein will be published in the Federal Register.) The plant quality control system shall be subject to periodic review, and the approval of such system may be terminated in accordance with § 318.4(g)(2) of this subchapter.

5. Section 319.6 (9 CFR 319.6) is revised and reorganized to read as follows:

§ 319.6 Limitations with respect to use of Mechanically Separated (Species).

(a) Meat food products required to be prepared from one species shall not contain Mechanically Separated (Species) of any other species.

(b) Mechanically Separated (Species) described in § 319.5 that has a protein content of not less than 14 percent and a fat content of not more than 30 percent may constitute up to 20 percent of the livestock and poultry product portion of any meat food product except those listed in paragraph (d) of this section.

(c) Mechanically Separated (Species) for processing described in § 319.5 may constitute up to 20 percent of the livestock and poultry product portion of any meat food product that is subject to a definition and standard of identity or composition in Part 319 which establishes a maximum limit on the fat

content of such meat food product except those listed in paragraph (d) of this section.

(d) Mechanically Separated (Species) and Mechanically Separated (Species) for processing described in § 319.5 shall not be used in baby, junior, or toddler foods, ground beef, hamburger, fabricated steaks (§ 319.15 (a), (b), and (d)), barbecued meats (§ 319.80), roast beef-parboiled and steam roasted (§ 319.81), corned (cured) beef cuts (§§ 319.100-319.103) certain cured pork products (§§ 319.104 (a)-(e) and 319.106), tripe with milk (§ 319.308), lima beans with ham and similar products (§ 319.310), beef with gravy and gravy with beef (§ 319.313), and meat pies (§ 319.500).

6. Section 319.140 (9 CFR 319.140) is amended by adding the following sentence at the end of that section:

§ 319.140 Sausage.

* * * Sausage may contain Mechanically Separated (Species) used in accordance with § 319.6.

§§ 319.15, 319.104, 319.105, 319.141—319.145, 319.180, 319.182, 319.260, 319.261, 319.280, 319.281, 319.300—319.307, 319.311, 319.312, 319.600, 319.760, 319.762 [Amended]

7. Sections 319.15(c) *Beef patties*, 319.104(f) *Pressed ham, spiced ham, and similar products*, 319.105(b)(10) *Chopped ham*, 319.141 *Fresh pork sausage*, 319.142 *Fresh beef sausage*, 319.143 *Breakfast sausage*, 319.144 *Whole hog sausage*, 319.145(a) (1)-(3) *Italian sausage products*, 319.180 (a)-(c) *Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst, and similar products*, § 319.182 *Liver sausage and braunschweiger*, § 319.260 *Luncheon meat*, § 319.261 *Meat loaf*, § 319.280 *Scrapple*, § 319.281(a)(1) *Bockwurst*, § 319.300 *Chili con carne*, § 319.301 *Chili con carne with beans*, § 319.302 *Hash*, § 319.303(b)(9) *Corned beef hash*, § 319.304 *Meat stews*, § 319.305 *Tamales*, § 319.306 *Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products*, § 319.307 *Spaghetti sauce with meat*, § 319.311 *Chow mein vegetables with meat and chop suey vegetables with meat*, § 319.312 *Pork with barbecue sauce and beef with barbecue sauce*, § 319.600 (a) and (b) *Pizza*, § 319.760(a) *Deviled ham, deviled tongue, and similar products*, and § 319.762 *Ham spread, tongue spread and similar products* (9 CFR 319.15(c), 319.104(f), 319.105(b)(10), 319.141-319.144, 319.145(a) (1)-(3), 319.180(a)-(c), 319.182, 319.260, 319.261, 319.280, 319.281(a)(1), 319.300-319.302, 319.303(b)(9), 319.304-

319.307, 319.311, 319.312, 319.600 (a) and (b), 319.760(a), and 319.762) are amended by replacing the term "Mechanically Processed (Species) Product" with the term "Mechanically Separated (Species)".

8. Section 319.141 (9 CFR 319.141) is further amended by revising the second sentence as follows:

§ 319.141 Fresh pork sausage.

* * * The finished product shall not contain more than 50 percent fat. * * *

9. Section 319.143 (9 CFR 319.143) is further amended by revising the second sentence as follows:

§ 319.143 Breakfast sausage.

* * * The finished product shall not

contain more than 50 percent fat. * * *

10. Section 319.144 (9 CFR 319.144) is further amended by revising the second sentence as follows:

§ 319.144 Whole hog sausage.

* * * The finished product shall not contain more than 50 percent fat. * * *

§ 319.145 [Amended]

11. Paragraph (a)(3) of § 319.145 (9 CFR 319.145) is further amended by moving the second sentence to the end of the paragraph.

12. Section 319.160 (9 CFR 319.160) is amended by revising the third sentence as follows:

§ 319.160 Smoked pork sausage.

* * * The finished product shall not

contain more than 50 percent fat. * * *

§ 319.281 [Amended]

13. Paragraph (a)(1) of § 319.281 (9 CFR 319.281) is further amended by moving the second sentence to the end of the paragraph.

§ 319.305 [Amended]

14. Section 319.305 (9 CFR 319.305) is further amended by moving the second sentence to the end of the section.

Done at Washington, D.C., on June 22, 1982.

C. W. McMillan,

Assistant Secretary for Marketing and Inspection Services.

[FR Doc. 82-17197 Filed 6-28-82; 8:45 am]

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Registered Federal Trade

**Tuesday
June 29, 1982**

Part III

Environmental Protection Agency

**Inorganic Chemicals Manufacturing Point
Source Category Effluent Limitations
Guidelines, Pretreatment Standards, and
New Source Performance Standards**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 415

[WH-FRL 2080-6]

Inorganic Chemicals Manufacturing Point Source Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This regulation limits the discharge of pollutants into navigable waters and into publicly owned treatment works by existing and potential new sources that manufacture certain inorganic chemicals.

The Clean Water Act and a consent decree require EPA to issue this regulation.

The purpose of this regulation is to specify effluent limitations for "best practicable technology", "best available technology", and "new source performance standards" for direct dischargers and to establish pretreatment standards for indirect dischargers.

DATES: In accordance with 40 CFR 100.01 (45 FR 26048), this regulation shall be considered issued for purposes of judicial review at 1:00 p.m. Eastern time on July 13, 1982. These regulations shall become effective (August 12, 1982).

Under Section 509(b)(1) of the Clean Water Act judicial review of this regulation 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.

ADDRESSES: The basis for this regulation is detailed in four major documents. See Supplementary Information under "XVI Availability of technical information" for a description of each document.

Technical information may be obtained by writing to Dr. Thomas E. Fielding, Effluent Guidelines Division (WH-552), EPA, 401 M Street, SW., Washington, D.C. 20460, or through calling (202) 426-2582. Copies of the technical documents may be obtained from the National Technical Information Service, Springfield, Virginia 22161 (703/487-6000). The economic analysis may

also be obtained from the National Technical Information Service.

The Record will be available for public review three weeks after the effective date in EPA's Public Information Reference Unit, Room 2004 (Rear) (EPA Library), 401 M Street, SW., Washington, D.C. The EPA information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Dr. Thomas E. Fielding, (202) 426-2582.
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I. Legal Authority

This regulation is being promulgated under the authority of Sections 301, 304,

306, 307, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. 1251 *et seq.*, as amended by the Clean Water Act of 1977, Pub. L. 95-217), also called the "Act". It is also being promulgated in response to the Settlement Agreement in *Natural Resources Defense Council, Inc., v. Train*, 9 ERC 2120 (D.D.C. 1976), modified, 12 ERC 1833 (D.D.C. 1979).

II. Scope of This Rulemaking

The inorganic chemicals manufacturing industry is included within the U.S. Department of Commerce, Bureau of the Census, Standard Industrial Classification (SIC) 281, Industrial Inorganic Chemicals. The final regulation applies to parts of subgroups 2812, Alkalies and Chlorine; 2813, Industrial Gases; 2816, Inorganic Pigments; and 2819, Industrial Inorganic Chemicals, Not Elsewhere Classified.

The most important pollutants or pollutant parameters found in inorganic industry wastewaters are: (a) toxic pollutants (chromium, nickel, lead, mercury, copper, cadmium, zinc, and cyanide); (b) conventional pollutants (TSS and pH); and (c) nonconventional pollutants (COD, fluoride, iron, and ammonia). EPA's 1973 to 1976 round of rulemaking emphasized the achievement of best practicable technology currently available (BPT) by July 1, 1977. In general, BPT represents the average of the best existing performances of well-known technologies for control of familiar (i.e., "classical") pollutants.

In contrast, this round of rulemaking aims for the achievement by July 1, 1984, of the best available technology economically achievable (BAT) that will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants. At a minimum, BAT represents the best economically achievable performance in any industrial category or subcategory. Moreover, as a result of the Clean Water Act of 1977, the emphasis of EPA's program has shifted from "classical" pollutants to the control of a lengthy list of toxic substances.

EPA is promulgating BPT, BCT, BAT, NSPS, and PSNS for the following 6 subparts:

- subpart V (Titanium Dioxide)
 - subpart AH (Chrome Pigments)
 - subpart AJ (Copper Sulfate)
 - subpart AP (Hydrogen Cyanide)
 - subpart AU (Nickel Sulfate)
 - subpart BB (Sodium Bisulfite)
- BPT, BAT, NSPS, and PSNS for the following 2 subparts:
- subpart F (Chlor-Alkali Diaphragm Cell Process)
 - subpart H (Hydrofluoric Acid)

BCT, BAT, NSPS, and PSNS for the following 2 subparts:

- subpart F (Chlor-Alkali Mercury Cell Process)
 - subpart Q (Sodium Dichromate) and BPT, BCT, BAT, and NSPS for the following subpart:
 - subpart W (Aluminum Fluoride)
- PSES are being promulgated for the following subparts:
- subpart F (Chlor-Alkali Diaphragm Cell Process)
 - subpart AH (Chrome Pigments)
 - subpart AJ (Copper Sulfate)
 - subpart AU (Nickel Sulfate)

Technical amendments consisting of non-substantive format changes are being promulgated for the remaining subparts. At the request of the industry, EPA is reconsidering the BAT limitations in the Calcium Chloride (subpart D), Sodium Chloride-Brine Mining Process (subpart P), and Sodium Sulfite (subpart T) subparts. We intend to address separately the issues raised pertaining to these subparts in the near future.

III. Summary of Legal Background

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (Section 101(a)). To implement the Act, EPA was to issue effluent standards, pretreatment standards, and new source performance standards for industry dischargers.

The Act included a timetable for issuing these standards. However, EPA was unable to meet many of the deadlines and, as a result, in 1976, it was sued by several environmental groups. In settling this lawsuit, EPA and the plaintiffs executed a court-approved "Settlement Agreement". This Agreement required EPA to develop a program and adhere to a schedule in promulgating effluent limitations guidelines, and pretreatment standards for 65 "priority" pollutants and classes of pollutants, for 21 major industries. See *Natural Resources Defense Council, Inc. v. Train*, 9 ERC 2120 (D.D.C. 1976), modified, 12 ERC 1833 (D.D.C. 1979).

Many of the basic elements of this Settlement Agreement program were incorporated into the Clean Water Act of 1977. Like the Agreement, the Act stressed control of toxic pollutants, including the 65 "priority" pollutants. In addition, to strengthen the toxic control program, Section 304(e) of the Act authorizes the Administrator to prescribe "best management practices" (BMPs) to prevent the release of toxic and hazardous pollutants from plant site runoff, spillage or leaks, sludge or waste

disposal, and drainage from raw material storage associated with, or ancillary to, the manufacturing or treatment process.

Under the Act, the EPA program is to set a number of different kinds of effluent limitations. These are discussed in detail in the proposed regulation and Development Document. The following is a brief summary:

1. Best Practicable Control Technology (BPT). BPT limitations are generally based on the average of the best existing performance by plants of various sizes, ages, and unit processes within the industry or subcategory.

In establishing BPT limitations, we consider the total cost of applying the technology in relation to the effluent reduction derived, the age of equipment and facilities involved, the process employed, the engineering aspects of the control technologies, process changes, and non-water-quality environmental impacts (including energy requirements). We balance the total cost of applying the technology against the effluent reduction.

2. Best Available Technology (BAT). BAT limitations, in general, represent the best existing performance in the industrial subcategory or category. The Act establishes BAT as the principal national means of controlling the direct discharge of toxic and nonconventional pollutants to navigable waters.

In arriving at BAT, the Agency considers the age of the equipment and facilities involved, the process employed, the engineering aspects of the control technologies, process changes, the cost of achieving such effluent reduction, and non-water-quality environmental impacts. The Administrator retains considerable discretion in assigning the weight to be accorded these factors.

3. Best Conventional Pollutant Control Technology (BCT). The 1977 Amendments added Section 301(b)(2)(E) to the Act establishing "best conventional pollutant control technology" (BCT) for discharge of conventional pollutants from existing industrial point sources. Conventional pollutants are those defined in Section 304(a)(4) [biological oxygen demanding pollutants (BOD₅), total suspended solids (TSS), fecal coliform and pH], and any additional pollutants defined by the Administrator as "conventional" [oil and grease, 44 FR 44501, July 30, 1979].

BCT is not an additional limitation but replaces BAT for the control of conventional pollutants. In addition to other factors specified in section 304(b)(4)(B), the Act requires that BCT limitations be assessed in light of a two part "cost-reasonableness" test.

American Paper Institute v. EPA, 660 F.2d 954 (4th Cir. 1981). The first test compares the cost for private industry to reduce its conventional pollutants with the costs to publicly owned treatment works for similar levels of reduction in their discharge of these pollutants. The second test examines the cost-effectiveness of additional industrial treatment beyond BPT. EPA must find that limitations are "reasonable" under both tests before establishing them as BCT. In no case may BCT be less stringent than BPT.

EPA published its methodology for carrying out the BCT analysis on August 29, 1979 (44 FR 50732). In the case mentioned above, the Court of Appeals ordered EPA to correct data errors underlying EPA's calculation of the first test, and to apply the second cost test. (EPA had argued that a second cost test was not required).

4. New Source Performance Standards (NSPS). NSPS are based on the best available demonstrated technology. New plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies.

5. Pretreatment Standards for Existing Sources (PSES). PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of well-operated publicly owned treatment works (POTW) with secondary treatment installed. They must be achieved within three years of promulgation. The Clean Water Act of 1977 requires pretreatment for toxic pollutants that pass through the POTW in amounts that would violate direct discharger effluent limitations or interfere with the POTW's treatment process or chosen sludge disposal method. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based, analogous to the best available technology for removal of toxic pollutants. EPA has generally determined that there is pass through of pollutants if the percent of pollutants removed by a well-operated POTW achieving secondary treatment is less than the percent removed by the BAT model treatment system. The general pretreatment regulations, which served as the framework for the categorical pretreatment regulations are found at 40 CFR Part 403 (43 FR 27736 June 26, 1978; 46 FR 9462 January 28, 1981).

We are promulgating PSES for the Chlor-Alkali (Diaphragm Cell) and Chrome Pigments subcategories and we are amending the existing PSES for the Copper Sulfate and Nickel Sulfate

subcategories. We are excluding the Chlor-Alkali (Mercury Cell), Hydrofluoric Acid, Sodium Dichromate, Titanium Dioxide, Hydrogen Cyanide, and Sodium Bisulfite subcategories from national categorical PSES under the provisions of Paragraph 8(b) of the Settlement Agreement because the toxic pollutants in discharges to POTWs from sources in those subcategories are below treatable levels or are so insignificant as not to justify developing pretreatment standards. We are not promulgating PSES for the Aluminum Fluoride subcategory because a well-operated POTW with secondary treatment installed achieves better percent removal of toxic pollutants than is provided by the BAT model treatment system for this subcategory.

6. Pretreatment Standards for New Sources (PSNS). Like PSES, PSNS are to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operation of the POTW. PSNS are to be issued at the same time as NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating PSES.

IV. Methodology and Data Gathering Efforts

The data gathering efforts and methodology used in developing the proposed regulations were summarized in the "Preamble to the Proposed Inorganic Chemicals Manufacturing Point Source Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards" (45 FR 49450, July 24, 1980). The *Development Document for Effluent Guidelines, New Source Performance Standards, and Pretreatment Standards for the Inorganic Chemicals Manufacturing Point Source Category* greatly expands and details this summary, and includes the use of new data we acquired since July 1980. This new data includes:

(1) a contractor's report prepared in July 1980 entitled *Treatability Studies for the Inorganic Chemicals Manufacturing Point Source Category*, EPA 440/1-80/103, (2) *Treatability Manual, Volume III—Technologies for Control/Removal of Pollutants*, EPA 600/8-80-042c, and (3) public comments on the draft development document, the proposed rule, and the treatability studies. The treatability studies were issued approximately the same time as the draft development document, but the results of the treatability studies were

not available in time to affect the proposed rules.

Each of those sources affected the final regulation. After receiving information from the treatability studies, we reevaluated treatment technologies for particular subcategories, which, in turn, led to changes in the technological basis for parts of the regulation. The information in the treatability manual added data to existing treatability information for the final development document. On the basis of industry comments, we decided not to regulate several toxic metals which are adequately controlled by the technologies on which other limitations are based. The comments were also the basis for changes in the control technology option for BAT in certain subcategories.

V. Control Treatment Options and Technology Basis for Final Regulations

A. Control Treatment Options

The control and treatment technologies that we investigated for use in this industry are enumerated below. Not all apply to all subcategories. Options 1 through 8 are the basis for this regulation. We investigated options 9 through 13 but rejected them because of high capital and operating costs, lack of use in the industry, or lack of performance data.

Option 1—Equalization, alkaline precipitation, and settling or clarification to remove toxic and other metals and fluorides.

Option 2—Addition of dual-media filtration to Option 1 to remove additional precipitated toxic metals.

Option 3—Sulfide precipitation to precipitate additional mercury, lead, copper, silver, cadmium, and arsenic.

Option 4—Use of coagulants to improve the settling or filtering of the metal precipitates generated in Options 1, 2, and 3.

Option 5—Sulfur dioxide, ferrous iron, or sulfide reduction to reduce hexavalent chromium to trivalent chromium in preparation for alkaline precipitation.

Option 6—Air oxidation to reduce COD, to oxidize ferrous to ferric iron to make it settleable, and to coprecipitate additional toxic metals.

Option 7—Alkaline chlorination, which raises pH to 10-11 and adds chlorine gas, to convert toxic cyanide to the less toxic cyanate.

Option 8—Dechlorination, which uses thermal, chemical, or catalytic decomposition to destroy free chlorine.

Option 9—Breakpoint chlorination, which adds more chlorine to Option 7 to

convert cyanate to carbon dioxide and ammonia.

Option 10—Carbon adsorption, which uses beds of granular activated carbon to remove metals and/or organic materials.

Option 11—Xanthate precipitation, which uses a starch or cellulose xanthate to precipitate toxic metals.

Option 12—Ion exchange, which uses ion exchange resin beds to remove toxic metals from the waste stream.

Option 13—Membrane processes (ultrafiltration and reverse osmosis) in which a waste stream is directed under pressure through a membrane to remove inorganic pollutants from the wastes.

B. Technology Basis for Final Regulations

We are promulgating substantive changes to existing regulations for the 10 subcategories detailed below. Two of the subcategories are segmented, and specific regulations are promulgated for each segment. The Chlor-Alkali subcategory is divided into two segments: mercury cell plants and diaphragm cell plants. The Titanium Dioxide subcategory is divided into three segments: chloride process plants, sulfate process plants, and chloride-ilmene process plants.

1. Chlor-Alkali (Subpart F). Chlorine and its coproduct caustic soda (alkali) are produced by the electrolysis of a sodium or potassium chloride solution using either the mercury cell or diaphragm cell process, or both. The processes differ in cell design and in the quantity and quality of wastewater generated. Because of these differences, we consider them separately under the Chlor-Alkali subcategory.

(a) Mercury Cell Segment. (i) Background. The mercury cell process uses mercury to form the cathode of the electrolytic cell. This segment of the industry now has 25 plants, 23 of which are direct dischargers and two are indirect dischargers.

The process wastewater flow rate of a model mercury cell chlor-alkali plant is 2.1 m³/kkg. Mercury cell plant wastewater is derived from several sources: brine mud, cell room wastes, chlorine condensate, spent sulfuric acid, tail gas scrubber liquid, caustic filter washdown, and hydrogen condensate. The toxic pollutants in these wastewaters include antimony, arsenic, cadmium, chromium, copper, lead, mercury, nickel, silver, thallium and zinc.

(ii) Final Limits. The BPT limitations for the Chlor-Alkali (Mercury Cell) subcategory are now in effect, 40 CFR 415.62(a). We are not promulgating any

changes to the BPT regulation for this segment of the industry. The technology basis for the existing DPT is Option 3 for mercury-laden streams and Option 1 for brine muds. This treatment scheme involves sulfide precipitation and filtration of mercury-laden streams and neutralization and settling of brine muds. Of the 23 direct dischargers, 22 now have BPT technology installed. The remaining plant has treatment technology installed, but it is not the same as BPT technology and does not perform as well. The pollutants regulated under BPT are TSS, mercury, and pH.

While EPA has not yet proposed or promulgated a revised BCT methodology in response to the *American Paper Institute v. EPA* decision mentioned earlier, EPA is promulgating BCT limitations for this subcategory. These limits are identical to those for BPT. EPA is not promulgating any more stringent limitations since we have identified no technology option which would remove significant additional amounts of conventional pollutants. The dechlorination technology added to BPT for BAT does not remove additional conventional pollutants. As BPT is the minimal level of control required by law, no possible application of the BCT cost tests could result in BCT limitations lower than those promulgated today. Accordingly, there is no need to wait until EPA revises the BCT methodology before promulgating BCT limitations.

We are promulgating BAT limitations based on the technology basis for BPT plus Option 6 (dechlorination). While the technology basis for BPT and BAT limitations is the same for removal of mercury, the BAT limitation on mercury is more stringent. The more stringent limitation is based on recently submitted industry data. All plants meeting the BPT limitations can also meet the BAT limitations. The more stringent limitations, therefore, do not result in additional costs. Dechlorination is known to be in place at two plants in this segment of the industry. The chlorine limitations are based on long-term monitoring data. Dechlorination will remove 2.4 million pounds per year of chlorine from the effluent at an annual cost of \$1.8 million per year. We considered adding Option 10 (carbon adsorption) but did not because of its high cost and questionable performance in this industry. Pollutants regulated under BAT limitations are mercury and total residual chlorine.

We have previously promulgated NSPS (39 FR 9616, March 12, 1974) which were equal to BPT. However, we are now amending those standards and

setting NSPS equal to the new BAT limitations. Pollutants regulated under NSPS are TSS, mercury, total residual chlorine, and pH.

We are promulgating PSNS that are equal to NSPS limitations on mercury because the direct discharge NSPS standard provides better removal of mercury than is achieved by a well-operated POTW with secondary treatment installed and hence mercury will pass through the POTW in the absence of pretreatment. Dechlorination is unnecessary because POTW influent often is chlorinated. For the reasons stated below, we are excluding the subcategory from categorical PSES.

(iii) Changes from Proposal. We have deleted limitations for all toxic metals except mercury because the technology necessary to comply with the effluent limitations and standards established for mercury effectively controls the other toxic metal pollutants present in the untreated wastewater. We have also revised the limitations for chlorine based on new industry data and comment, and the limitations are now less stringent.

We proposed categorical PSES equal to BAT for toxic metals for this subcategory. However, we are not promulgating PSES for this subcategory. Instead, the subcategory is excluded from categorical PSES under the provisions of paragraph 8(b) of the Settlement Agreement because the discharge of total toxic metals to POTWs from the two existing sources combined is below treatable levels and amounts to only 40 pounds per year.

(b) Diaphragm Cell Segment. (i) Background. The diaphragm cell segment of the industry now has 36 plants, 35 of which are direct dischargers and 1 is an indirect discharger.

The diaphragm cell contains a porous asbestos diaphragm separating the anode from the cathode. In the past, the predominant material used for anodes was graphite, with lead providing an electrical contact and support. In recent years, many graphite anodes have been replaced by stabilized metal anodes of titanium with a platinum or ruthenium oxide coating. The advantages of using metal anodes instead of graphite anodes are increased power efficiency of the cells, longer anode life, and a reduction in potential pollutant loads of lead and chlorinated organics.

The process wastewater flow rate for a model diaphragm cell chlor-alkali plant is 8.8 m³/kkg. The wastewater is derived from cell room wastes, chlorine cooling condensate, spent sulfuric acid, tail gas scrubber liquid, filter

backwashes, hydrogen condensate, and barometric condensers. The toxic pollutants in these wastewaters include antimony, arsenic, cadmium, chromium, copper, lead, nickel, silver, thallium, and zinc.

(ii) Final Limits. BPT limitations for the Chlor-alkali (Diaphragm Cell) subcategory are now in effect, 40 CFR 415.62(b). However, we are revising the BPT limitations because new data demonstrates that the flow in this segment is 8.8 m³/kkg, not the 3.3 m³/kkg previously used. The new lead limit is based on an analysis of long-term self-monitoring data at one plant that uses graphite anodes. The TSS limit is based on achieving 35 mg/l by settling the effluent. The technology basis for BPT is equalization, alkaline precipitation, and settling. All plants in the subcategory have installed BPT technology or have installed metal anodes and meet the limitations without treatment. Pollutants regulated under the BPT limitations are TSS, copper, lead, nickel, and pH. EPA has determined that the BAT technology for this subcategory is capable of removing significant amounts of conventional pollutants. However, EPA has not yet proposed or promulgated a revised BCT methodology in response to the *American Paper Institute v. EPA* decision mentioned earlier. Thus, it is not now possible to apply the BCT cost test to this technology option. Accordingly, EPA is deferring a decision on the appropriate BCT limitations until EPA proposes the revised BCT methodology.

We are promulgating BAT limitations based on Options 2 and 8, which add dual-media filtration and dechlorination to BPT technology. Total residual chlorine limits are based on long-term monitoring data from the chlorine mercury cell subcategory. Two plants are known to have dechlorination treatment systems. The lead, nickel, and copper limits are based on published treatability data and data on industrial wastewater treatment system performance. Three of four plants that use metal anodes now meet the limitations for lead. One plant that was sampled meets the limitations for nickel. For all plants in this segment, BAT will remove an additional 240,000 pounds per year of toxic metals and 7.0 million pounds per year of residual chlorine at an annual cost of \$5.5 million per year. Pollutants regulated by the BAT limitations are copper, lead, nickel, and total residual chlorine.

We are promulgating NSPS that are equal to BAT limitations with the additional exclusion of lead in cell

construction. The limitations are based on published treatability data. The limitations for lead can be met by the use of metal anodes which new plants would probably use anyway because they are more efficient. Pollutants regulated under NSPS are TSS, lead, total residual chlorine, and pH.

We are promulgating PSES that are equal to BPT limitations and PSNS that are equal to NSPS except for dechlorination, which is unnecessary because POTW influent often is chlorinated. Pretreatment is necessary because the direct discharge standards provide better removal of lead, copper, and nickel than is achieved by a well-operated POTW with secondary treatment installed and hence these pollutants would pass through a POTW in the absence of pretreatment. PSES are being set equal to BPT, because the POTW achieves equal or greater removal of the toxic metals remaining after application of BPT (PSES) technology than is achieved by the filtration required by BAT.

(iii) Changes from Proposal. We have deleted limitations on all toxic metals except copper, lead, and nickel, because the technology necessary to comply with the effluent limitations and standards established for copper, lead, and nickel effectively controls the other toxic metal pollutants present in the untreated wastewater. We have revised the limitations for chlorine, copper, lead, and nickel based on new industry data and the results of our treatability study, and the limitations are now less stringent. We have deferred establishing BCT limitations pending development of a new BCT cost test.

PSES were proposed equal to BAT. PSES are now set equal to BPT, because the POTW achieves equal or greater removal of the toxic metals remaining after application of BPT (PSES) technology than is achieved by the filtration required by BAT. Thus, a filter is not required for PSES because there is no pass-through. See 46 FR 9462 (January 28, 1981).

2. Hydrofluoric Acid (Subpart H) (a) Background. Hydrofluoric acid, or hydrogen fluoride (HF), is produced as both anhydrous and aqueous products.

Fluorspar, mainly calcium fluoride (CaF_2), and sulfuric acid are the raw materials used for the manufacture of HF. The fluorspar and sulfuric acid react to form HF. This subcategory now has nine direct dischargers. There are no indirect dischargers.

The process wastewater flow rate for a model hydrofluoric acid plant is 96 m³/kg. Hydrofluoric acid plant wastewater sources include gypsum solids treatment wastes, drip acid,

noncontact cooling water, scrubber wastewater distillation wastes, and the treatment of other solid waste sources. The toxic pollutants in these wastewaters include antimony, arsenic, cadmium, chromium, copper, lead, mercury, nickel, selenium, thallium, and zinc.

(b) Final Limits. We are promulgating BPT limitations based on Option 1, which involves equalization, lime precipitation, and clarification or settling plus reuse of at least 43 percent of the effluent for kiln residue slurring. All nine plants in the industry have installed this technology. The BPT limitations for TSS and fluoride are based on long-term data from one plant that does not reuse treated wastewater. Five plants are meeting BPT limits, according to long-term self-monitoring data. Limitations for toxic metals are based on averaged effluent sampling data unless the observed pollutant concentration is below the treatability level cited in the literature. In such cases, the lowest applicable treatability level is used. Pollutants limited by the BPT limitations are TSS, fluoride, nickel, zinc, and pH. We are deferring promulgation of BCT for the reasons described in Section V.B.1.(b)(ii) above.

We are promulgating BAT limitations based on Option 1 plus reuse of at least 65 percent of the effluent for kiln residue slurring. This level of treatment includes BPT plus recycle to remove additional toxic metals and fluorides. This technology will remove an additional 35,000 pounds per year of toxic metals at an annual cost of \$514,000 per year. The limitation for fluoride is based on long-term monitoring data from one plant that reuses 83 percent of the treated effluent. For toxic metals, the limitations are based on the reduced flow achieved by recycle. After conducting additional treatability studies, we concluded that adding dual-media filtration after alkaline precipitation and settling is not particularly effective in reducing final TSS, total fluoride and toxic metal concentrations. Hence we did not select Option 2 (addition of dual-media filtration) for BAT or NSPS.

We considered using treatment Option 3 (addition of sulfide precipitation) but did not because of the lack of performance data. We also considered using a variation of Option 2 that would substitute soda ash in the lime precipitation step and allow 90 percent recycle of effluent. We rejected this option because of its high cost. Pollutants regulated under BAT limitations are fluoride, nickel, and zinc.

We are promulgating NSPS equal to BAT. Pollutants limited by NSPS are TSS, fluoride, nickel, zinc, and pH.

We are promulgating PSNS that are equal to NSPS because NSPS provides better removal of nickel and zinc than is achieved by a well-operated POTW with secondary treatment installed and therefore these pollutants would pass through a POTW in the absence of pretreatment. Pollutants limited by PSNS are fluoride, nickel, and zinc. For the reasons described below we are excluding this subcategory from categorical PSES.

(c) Changes from Proposal. We have deleted limitations for all toxic metals except nickel and zinc because the technology necessary to comply with the effluent limitations and standards established for nickel and zinc effectively control the other toxic metal pollutants present in untreated wastewater. We have revised the limitations on fluoride, nickel, and zinc based on new industry data and the results of our treatability study, and they are now less stringent. We have deferred establishing BCT limitations pending development of a new BCT cost test.

We proposed PSES equal to BAT for this subcategory. However, there are no indirect dischargers in the subcategory, and we are excluding the subcategory from categorical PSES under the provisions of paragraph 8(b) of the Settlement Agreement.

3. Titanium Dioxide (Subpart V). Titanium dioxide (TiO_2) is manufactured by a chloride process, a sulfate process, and a chloride-ilmenite process. This subcategory is subdivided into three segments, one for each process, because of the difference in raw materials used, wastewater flows, and raw waste characteristics.

(a) Sulfate Process Segment. (i) Background. This subcategory now has four plants, all of which are direct dischargers. One plant discharges a portion of its waste to a municipal system.

Ilmenite is a low-grade titanium ore with a TiO_2 content varying from 45 to 60 percent. Ilmenite ore or slag containing titanium from iron production generally comprises the raw materials used for production of titanium dioxide by the sulfate process.

The process wastewater flow rate for a model plant using the TiO_2 sulfate process is 475 m³/kg. The process wastewater comes from digester sludge, copperas, strong acid waste, weak acid waste, scrubber waste, and wet milling waste. The toxic pollutants in these wastewaters are antimony, arsenic, cadmium, chromium, copper, lead, nickel, selenium, thallium, and zinc.

(ii) Final Limits. We are promulgating BPT limitations based on Option 1, which involves limestone precipitation, clarification, lime precipitation, and settling. One of the four plants in this segment of the industry now has BPT technology, and we based BPT limitations on this plant's performance and treatability data. BPT treatment will remove 330,000 pounds per year of toxic metals, 21,000 tons per year of TSS, and neutralize 48,000 tons per year of acid at an annual cost of \$8.8 million. Pollutants regulated under BPT limitations are TSS, chromium, nickel, and pH.

We are promulgating BAT limitations that are equal to BPT because additional treatment is too costly for existing plants. Toxic and nonconventional pollutants regulated under BAT are the same as for BPT. While EPA has not yet proposed or promulgated a revised BCT methodology in response to the *American Paper Institute v. EPA* decision mentioned earlier, EPA is promulgating BCT limitations for this subcategory. These limits are identical to those for BPT because the only technology option that removes significant amounts of conventional pollutants is not economically achievable. See the discussion of BAT under "Changes from Proposal" below. Removal of significant additional amounts of conventional pollutants can be achieved in this subcategory only if iron is also removed.

As BPT is the minimal level of control required by law, no possible application of the BCT cost tests could result in BCT limitations lower than those promulgated today. Accordingly, there is no need to wait until EPA revises the BCT methodology before promulgating BCT limitations.

We are promulgating NSPS and PSNS based on Option 1 plus Option 6, which adds oxidation of ferrous iron to ferric iron to improve settling and toxic metal removal. In addition to the toxic pollutants regulated under BPT, for the reasons described below we are regulating the non-conventional pollutant iron under NSPS and PSNS. We are also regulating TSS and pH under NSPS. We considered requiring a 55 percent waste recycle through the substitution of soda ash precipitation, but rejected it because its performance has not been demonstrated. PSNS are necessary because NSPS provides better removal of chromium, nickel, and iron than is achieved by a well-operated POTW with secondary treatment installed and therefore chromium, nickel, and iron would pass through the POTW in the absence of pretreatment. This subcategory is excluded from

categorical PSES for the reasons described below.

(iii) Changes from Proposal. We have deleted limitations on all toxic metals except chromium and nickel because the technology necessary to comply with the effluent limitations and standards established for chromium and nickel effectively controls the other toxic metal pollutants present in the untreated wastewater.

We decided not to regulate the non-conventional pollutant iron under BPT and BAT because of the increased cost of the treatment when iron is controlled and because the gypsum solids produced by the treatment with iron removal can be reused only if dissolved iron is not controlled. One plant has developed a market for reuse of the gypsum. We estimate that requiring iron removal at existing plants would increase treatment costs by up to 40 percent and generate large quantities of waste solids for disposal. Control of toxic metal pollutants will be adequate at existing plants even without an iron removal step.

We have revised the limitations on TSS, chromium, and nickel based on long-term performance data from a plant using the model treatment technology without iron removal, and they are now less stringent. An iron removal step added to BPT/BAT technology is retained for NSPS/PSNS because the additional treatment provides better removal of toxic metals, and the more stringent standards are unlikely to pose a significant barrier to entry. New sulfate process plants are unlikely because the two alternate processes are more economical. However, if a company did want to construct a new sulfate-process plant, a process change involving the recycle and reuse of the strong acid wastewater would likely be adopted. This process change would reduce production costs, and would also reduce the amount of strong acid wastewater treated and discharged by 70 to 90 percent. Reducing the flow of the strong acid wastewater reduces treatment costs substantially and also substantially reduces the amount of gypsum solids produced by treatment. With the smaller amount of gypsum solids produced, disposal of the solids as waste is competitive with sale of the solids for reuse, when cost of sales is considered. At least one company using the sulfate process is actively developing the recycle/reuse technology. One other company using the chloride-ilmenite process has recently built a new plant that discharges 50 percent less total wastewater than comparable plants.

We proposed PSES equal to BAT for this subcategory. However, the only wastewater discharged to the POTW from the one existing indirect discharger is a small portion of the weak acid stream. Based on data provided in response to Section 308 request, it is unlikely that this wastewater contains any toxic metals at treatable levels. Therefore, we are excluding this subcategory from categorical PSES under the provisions of paragraph 8(b).

(b) Chloride-ilmenite Process Segment. (i) Background. This subcategory now has three plants, all of which are direct dischargers.

The direct use of ilmenite ore for the manufacture of titanium dioxide pigments requires the application of either the sulfate process or the one-step ore beneficiation/chlorination process which we call the chloride-ilmenite process. Processes that involve a separate ore beneficiation step (either on-site or at the ore source) which result in an upgraded or a synthetic rutile product to be used as feed material for a chloride process are not considered chloride-ilmenite processes. A separate ore beneficiation process would be regulated under the Ore Mining and Dressing Category, and the manufacture of TiO₂ from an upgraded ilmenite or synthetic rutile would be in the same classification as a chloride process using natural rutile ore.

The process wastewater flow rate for a model plant using the titanium dioxide chloride-ilmenite process is 120 m³/kkg. The sources of wastewater include chlorination process waste, product finishing waste, and dilute acid waste. The toxic pollutants in this wastewater include antimony, arsenic, cadmium, chromium, copper, lead, nickel, selenium, thallium, and zinc.

(ii) Final Limits. We are promulgating BPT limitations based on Option 1, which involves limestone precipitation, primary clarification, lime precipitation, and settling. Selection of this option is based on the similarity of the toxic pollutants in these wastes to those in the titanium dioxide sulfate process wastes. We used flow data from existing plants using the chloride-ilmenite process and performance data from a plant using the sulfate process to establish the limitations. All three plants in this segment of the industry are achieving results comparable to BPT limitations. Pollutants regulated under final BPT limitations are TSS, chromium, nickel, and pH.

We are promulgating BAT limitations that are equal to BPT limitations because additional treatment is too costly for existing plants. Pollutants

regulated under BAT limitations are chromium and nickel. We are promulgating BCT limitations that are equal to BPT limitations for the reasons described in Section V.B.3.(a)(ii) above.

We are promulgating NSPS based on Options 1, 2, and 6. These options add iron removal, a dual-media filter, and a reduced wastewater flow level that is achievable only in newly constructed plants. One recently constructed plant is operating at this reduced flow. Pollutants regulated under NSPS are TSS, iron, chromium, nickel, and pH.

We are promulgating PSNS that are equal to NSPS because these standards provide better removal of iron, chromium and nickel than is achieved by a well-operated POTW with secondary treatment installed and therefore iron, chromium and nickel would pass through a POTW in the absence of pretreatment. Pollutants regulated under PSNS are iron, chromium, and nickel. For the reasons described below we are excluding this subcategory from categorical PSES.

(iii) Changes from Proposal. Since the limitations for the chloride-ilmenite process are based on data for the sulfate process, we made the same type of changes for the chloride-ilmenite process as were described previously for the sulfate process. We proposed PSES equal to BAT. However, since there are no indirect dischargers in this subcategory, we are excluding this subcategory from categorical PSES under the provisions of paragraph 8(b) of the Settlement Agreement.

(c) Chloride Process Segment. (i) Background. Six plants currently use the chloride process, all of which are direct dischargers.

In the chloride process, the raw materials used are rutile or upgraded ilmenite ore; both are relatively pure materials with a high titanium and low iron content. For upgrading ilmenite (FeTiO_3), a beneficiation process removes part or all of the iron. The wastes from the chloride process using direct, one-step beneficiation of ilmenite in titanium dioxide production are different from those produced using high-grade titanium ore (rutile or upgraded ilmenite).

The process wastewater flow rate for a model plant using the TiO_2 chloride process is 100 m³/kkg. The process wastewater sources include wastes from cooling chlorinator gas, chlorinator process tail gas scrubber waste, distillation bottoms, oxidation tail gas scrubber waste, and finishing operations waste. The toxic pollutants in these wastewaters include chromium, lead, nickel, and zinc.

(ii) Final Limits. We are promulgating BPT limitations based on Option 1, which involves equalization, alkaline precipitation, and settling or clarification. All six plants in this segment of the industry now have installed BPT technology. Limitations are based on sampling data and long-term data from a plant that is meeting the limits. Pollutants regulated by the BPT limitations are TSS, chromium, and pH.

For the reasons discussed in paragraph (iii) below, we are promulgating BAT limitations that are equal to BPT limitations. We are promulgating BCT limitations equal to BPT limitations for TSS for the reasons described in Section V.B.3.(a)(ii) above.

We are promulgating NSPS and PSNS based on Option 2. Limitations for this level of treatment are based on published treatability data for filtration of precipitated wastes. Pollutants limited by NSPS regulations are TSS, iron, chromium, and pH. Pollutants regulated by PSNS are iron and chromium. These pollutants are regulated because NSPS provides better removal of iron and chromium than is achieved by a well-operated POTW with secondary treatment installed and therefore iron and chromium would pass through the POTW in the absence of pretreatment.

The Agency also considered adding Option 3 (sulfide precipitation) but did not do so because that option does not effectively remove chromium from the wastewater. We are excluding this subcategory from categorical PSES for the reasons described below.

(iii) Changes from Proposal. We decided to delete the limitations on iron for existing sources because of the increased cost of treatment when iron is controlled and because two plants operate both the chloride process and the sulfate process and send wastewater from both processes to the same treatment facility. In order for these two plants to treat the chloride process wastewater to remove iron, they would either also have to treat the sulfate process wastewater to remove iron or undertake a massive reconstruction of the treatment facility. Such a reconstruction or removal of iron in the sulfate process would wipe out the recycle benefits and treatment cost reduction associated with the final BPT/BAT limitations for the sulfate process, and would probably result in the closure of the two sulfate process lines, with attendant increase in unemployment. Control of toxic metal pollutants will be adequate at existing plants even without an iron removal step. We have revised the limitations on TSS and chromium

because of the change in treatment system and they are now less stringent.

For NSPS, we have revised the limitations on TSS, iron and chromium, based on new data; the iron and TSS limitations are more stringent while the chromium limitation is less stringent. NSPS are based on the addition of an iron removal step to BPT/BAT treatment. New plants can achieve significant reductions in wastewater flow, thus reducing overall treatment costs, even with the inclusion of the iron-removal step.

We proposed PSES equal to BAT for this subcategory. However, since there are no indirect dischargers in this subcategory, we are not promulgating PSES but are instead excluding this subcategory from categorical PSES under the provisions of paragraph 8(b) of the Settlement Agreement.

4. Aluminum Fluoride (Subpart W) (a) Background. The subcategory now has 5 plants, all of which are direct dischargers.

This regulation applies only to the dry process for the manufacture of aluminum fluoride, in which partially dehydrated alumina hydrate is reacted with hydrofluoric acid gas.

The process wastewater flow rate for a model aluminum fluoride plant is 11.9 m³/kkg. The process wastewater comes from noncontact cooling water, floor and equipment washings, scrubber wastewater, and solid waste handling. The toxic pollutants in this wastewater include arsenic, selenium, chromium, copper, lead, mercury, nickel, zinc, cadmium, antimony, and beryllium.

(b) Final Limits. We are promulgating BPT limitations based on treatment Option 1, which includes equalization, lime precipitation, and settling. All plants in this subcategory now have BPT technology. Limitations for TSS and fluoride are based on the similarity of the wastes to those in the Hydrofluoric Acid subcategory. Limitations for chromium and nickel are based on published treatability data. Pollutants regulated under BPT limitations are TSS, fluoride, chromium, nickel, and pH.

We are promulgating BAT limitations that are equal to the BPT limitations because additional treatment is too costly. The limitation for fluoride is based on the similarity of wastes to those of the Hydrofluoric Acid Subcategory. The limitations for chromium and nickel are based on published treatability data. After conducting additional treatability studies we concluded that adding dual-media filtration after alkaline precipitation and settling is not particularly effective in reducing total

fluoride or toxic metal concentrations. Hence, we did not select Option 2 (addition of dual-media filtration) for BAT. Pollutants regulated under BAT limitations are fluoride, nickel, and chromium. While EPA has not yet proposed or promulgated a revised BCT methodology in response to the *American Paper Institute v. EPA* decision mentioned earlier, EPA is promulgating BCT limitations for this subcategory. These limits are identical to those for BPT. EPA is not promulgating any more stringent limitations since we have identified no technology option which would remove significant additional amounts of conventional pollutants. As BPT is the minimal level of control required by law, no possible application of the BCT cost tests could result in BCT limitations lower than those promulgated today. Accordingly, there is no need to wait until EPA revises the BCT methodology before promulgating BCT limitations.

We are promulgating NSPS that are equal to BAT/BPT limitations. Pollutants regulated under NSPS are TSS, fluoride, chromium, nickel, and pH.

We are not promulgating PSES and PSNS because a well-operated POTW with secondary treatment installed provides equal or better removal of chromium and nickel than is achieved by BAT for this subcategory, and therefore there is no pass through of these toxic pollutants. There are no indirect dischargers in this subcategory.

We considered using Option 3 (sulfide precipitation) and requiring the use of soda ash to increase recycle. However, we rejected these options because they remove only small additional amounts of toxic pollutants in this subcategory.

(c) Changes from Proposal. The proposed regulations specified Option 2 for BAT. We have since established that adding dual-media filtration is ineffective in removing total fluoride or toxic metals. Therefore, the technology basis for BAT is Option 1 in this final rule. BAT limitations will now be equal to BPT in this subcategory. We are not promulgating PSES and PSNS for Aluminum Fluoride in this final rule, because a POTW provides equal or better removal of chromium and nickel (the only toxic pollutants regulated under BAT for this subcategory) than is achieved by BAT for this subcategory. Therefore, there is no pass through of these toxic pollutants in the Aluminum Fluoride subcategory.

5. Chrome Pigments (Subpart AH). (a) Background. This subcategory has 12 plants, 4 of which are direct dischargers and 8 are indirect dischargers.

The following products are regulated in this subcategory:

Anhydrous chrome oxide is almost pure chromium oxide (Cr_2O_3) and the commercial grade consists of a minimum of 98.5 percent Cr_2O_3 . It is prepared by calcination of sodium dichromate with sulfur or carbon.

Hydrous chromium oxide ($\text{Cr}_2\text{O}_3 \cdot 2\text{H}_2\text{O}$ or $\text{Cr}_2\text{O}(\text{OH})_4$), also known as chromium hydrate and Guigets Green, is a brilliant blue green. It is made by reacting sodium dichromate with boric acid.

Chrome yellow is made by reacting sodium dichromate, caustic soda, and lead nitrate, forming lead chromate.

Molybdenum orange is made by the coprecipitation of lead chromate (PbCrO_4) and lead molybdate (PbMoO_4).

Chrome greens are a coprecipitate of chrome yellow and iron blues. Iron blues are manufactured by reacting an aqueous solution of iron sulfate and ammonium sulfate with sodium ferrocyanide. The precipitate formed is separated and oxidized with sodium chlorate or sodium chromate to form iron blues ($\text{FeNH}_4\text{Fe}(\text{CN})_6$). Chrome green is produced by mechanically mixing chrome yellow and iron blue pigments in water.

Zinc yellow, also called zinc chromate, has the approximate composition $4\text{ZnO} \cdot \text{K}_2\text{O} \cdot 4\text{CrO}_3 \cdot 3\text{H}_2\text{O}$. It is made by reacting zinc oxide, hydrochloric acid, sodium dichromate, and potassium chloride.

The process wastewater flow rate for a model plant that produces chrome pigments is 105 m³/kg. Some variation in the wastewater sources may occur depending on the particular type of chrome pigment being produced. The sources generally include filter backwash, equipment washdown, and scrubber discharges. The toxic pollutants in this wastewater are antimony, cadmium, chromium, copper, lead, nickel, zinc, mercury, and cyanide.

(b) Final Limits. We are promulgating BPT limitations based on treatment Option 2 plus Option 5. This treatment requires reductions of hexavalent chromium followed by alkaline precipitation, clarification, and filtration. Of the four direct dischargers in this subcategory, one now has installed BPT technology. This plant represents a significant portion of the subcategory production, and its performance is the basis for the limitations. One other direct discharger, with a different treatment system, meets the promulgated BPT/BAT limitations. Other plants have no treatment or inadequate treatment of their wastes. This technology will remove 2,400,000 pounds per year of toxic metals from the effluent of direct and indirect dischargers, at an annual cost of \$7.8 million.

Pollutants regulated under BPT limitations are TSS, chromium, lead, zinc, and pH.

We are promulgating BAT limitations equal to BPT limitations, because the cost of additional treatment is too high in relation to the additional removal that could be achieved. Chromium, which is the primary toxic metal pollutant, is not affected by the next higher level of treatment considered, sulfide precipitation. Pollutants regulated under BAT limitations are chromium, lead, and zinc. We are promulgating BCT limitations that are equal to BPT limitations for the reasons described in Sections V.B.4.(b) above.

We are promulgating NSPS equal to BPT limitations for those reasons mentioned above in regard to BAT. Pollutants regulated under NSPS, are TSS, chromium, lead, zinc, and pH.

We are promulgating PSES and PSNS that are equal to BPT/BAT limitations because BPT provides better removal of chromium, lead, and zinc than is achieved by a POTW, and, therefore, without pretreatment these toxic pollutants would pass through a well-operated POTW with secondary treatment installed. In particular, 1.4 million pounds per year of hexavalent chromium would pass through in the absence of pretreatment. The pretreatment regulations promulgated today will remove over 1.3 million pounds of hexavalent chromium per year. Pollutants regulated under PSES and PSNS are chromium, lead, and zinc. Chrome Pigments plants discharging annually less than 210,000 m³ per year (55 million gallons per year) to a POTW are excluded from these categorical pretreatment standards and would be subject only to the general pretreatment standards in 40 CFR Part 403, for the reasons given in Section VI.

(c) Changes from Proposal. We have deleted limitations on all toxic metals except chromium, lead, and zinc because the technology necessary to comply with the limitations and standards established for chromium, lead, and zinc effectively controls the other toxic metal pollutants present in the untreated wastewater. Based on new industry data and our treatability study, we have revised the limitation for TSS, chromium, and zinc; the limitations for TSS are more stringent while the limitations for chromium and zinc are less stringent.

We are excluding small plants discharging less than 210,000 m³ process wastewater per year to POTW from compliance with these PSES. They will be subject only to the general pretreatment standards in 40 CFR Part

403. Plants discharging less than 210,000 m³ process wastewater per year produce less than 2000 kkg per year chrome pigments. There would be very significant economic impacts on this segment of the industry if it was required to comply with these PSES. See Section VI.

6. Hydrogen Cyanide (Subpart AP). (a) Background. This subcategory has 7 plants, 6 of which are direct dischargers and 1 is an indirect discharger. All plants in this subcategory now have BPT technology.

The Hydrogen Cyanide subcategory is confined to plants using the Andrusow process, in which air, ammonia, and methane are reacted to produce hydrogen cyanide. The raw materials are reacted to produce hydrogen cyanide and water at elevated temperatures.

The process wastewater flow rate for a model hydrogen cyanide plant is 57 m³/kkg. Plant wastewater comes from distillation bottoms, scrubber streams, and equipment washing. The only toxic pollutant in this wastewater is cyanide.

(b) Final Limits. We are promulgating BPT limitations based on Option 7, which uses alkaline chlorination to destroy cyanide amenable to chlorination, followed by clarification. The limitations are based on long-term data. Because one plant uses refrigeration to recirculate cooling water and thus reduce flow, we considered the low flow option. However, we rejected that method because it is energy intensive and doubles the treatment cost. Pollutants regulated under BPT limitations are TSS, cyanide A, total cyanide, and pH.

We are promulgating BAT limitations based on the addition of Option 8, dechlorination, to BPT technology. The dechlorination technology will remove 1.4 million pounds per year of chlorine at an annual cost of \$0.97 million. The chlorine limitations are based on the process wastewater flow rate for a model hydrogen cyanide plant and performance data from chloralkali industry plants which practice dechlorination. Pollutants regulated under BAT limitations are cyanide A, total cyanide, and total residual chlorine. We are promulgating BCT limitations that are equal to BPT limitations for the reasons described in Section V.B.1.(a)(ii) above.

We are promulgating NSPS that are equal to BAT limitations. Pollutants regulated under NSPS are TSS, cyanide A, total cyanide, total residual chlorine, and pH.

We are promulgating PSNS that are equal to BPT limitations for cyanide A and total cyanide because BPT provides

better removal of cyanide A and total cyanide than is achieved by a well-operated POTW with secondary treatment installed and, therefore, these pollutants would pass through a POTW in the absence of pretreatment.

Dechlorination is not needed because POTW influent often is chlorinated. Pollutants regulated under PSNS are cyanide A and total cyanide. We are not promulgating categorical PSES for this subcategory for the reasons described below.

(c) Changes from Proposal. We have revised the limitations on TSS, cyanide A, and chlorine based on new industry data, and they are now less stringent. Industry commented that the alkaline chlorination treatment to control cyanide amenable to chlorination does not control ammonia. We agree with this comment and have deleted limitations on ammonia in this final rule. No other economically achievable technologies were identified to control ammonia in this subcategory. We proposed PSES equal to BPT limitations for this subcategory. This subcategory is excluded from categorical PSES in this final rule under the provisions of paragraph 8(b) of the Settlement Agreement because the concentrations of toxic pollutants in the effluent to POTW from the one existing indirect discharger are below treatable levels.

7. Sodium Dichromate (Subpart Q). (a) Background. This subcategory has 3 plants, all of which are direct dischargers.

The starting materials for the preparation of sodium dichromate are chromite ore, limestone, and soda ash. When these materials are reacted, sodium chromate is formed, which is reacted with sulfuric acid to produce sodium dichromate.

The process wastewater flow rate for a model plant that produces sodium dichromate is 8.5 m³/kkg. Plant wastewater sources include spent ore treatment, cooling tower blowdown, and boiler blowdown. The toxic pollutants in this wastewater are chromium, copper, nickel, silver, zinc, selenium, and arsenic.

(b) Final Limits. BPT limitations for this subcategory are now in effect (40 CFR 415.172). The technology basis for the existing BPT limitations is ferrous iron reduction of hexavalent chromium, followed by alkaline precipitation of metals and clarification. All three plants in this subcategory now have BPT technology. Pollutants regulated under BPT limitations are TSS, total chromium, hexavalent chromium, nickel, and pH.

We are promulgating BAT limitations equal to BPT because the cost of additional removal is too high.

Pollutants regulated under BAT limitations are total chromium, hexavalent chromium, and nickel. We are promulgating BCT limitations equal to BPT for the reasons described in Section V.B.4.(b) above.

NSPS are now in effect for this subcategory (40 CFR 415.175). We have decided to amend the NSPS standards to set the TSS limitation equal to BPT, because additional technology does not remove significant additional amounts of a TSS. Pollutants regulated under NSPS are TSS, total chromium, hexavalent chromium, nickel, and pH.

We are not promulgating categorical PSES for this subcategory for the reasons described below.

PSNS regulations are now in effect, 40 CFR 415.176. Pollutants regulated under PSNS are total chromium, hexavalent chromium, and nickel. We are not amending these standards.

(c) Changes from Proposal. The proposed BAT regulation was based on Option 2 plus Option 5, that is, a filter was to be used to "polish" the effluent from clarification. The final BAT regulation is based on Option 1 plus Option 5 and therefore BAT limitations are equal to the BPT limitations, because the cost of the additional treatment provided by Option 2 is too high. We added limitations for nickel to the BPT limitations because it provides a means of controlling the group of toxic metals removed at slightly higher pH than chromium. We included limitations for nickel under BAT at the time of proposal. The BPT limitations for nickel are also based on Option 1 plus Option 5. We proposed PSES equal to BAT. However, since there are no indirect dischargers in this subcategory, we are not promulgating PSES but are instead excluding this subcategory from categorical PSES under the provisions of paragraph 8(b) of the Settlement Agreement.

8. Copper Sulfate (Subpart AJ). (a) Background. Of the 16 plants, 10 report they have no discharge of copper sulfate process wastewater, 5 are direct dischargers, and 1 is an indirect discharger.

Copper sulfate is produced by reacting copper with sulfuric acid, air, and water. Various forms of copper feed material are used, from pure copper to copper slag. The purity of raw materials significantly affects the quality and quantity of raw waste generated.

If pure copper is used as a raw material, there is little or no wastewater. If impure copper feed is used, a wastewater containing significant amounts of metal impurities is generated.

The process wastewater flow rate for a model plant that produces copper sulfate is 0.94 m³/kkg. Plant wastewater sources include washdown water, mother liquor purges, and sludge treatment. The toxic pollutants in this wastewater are antimony, arsenic, cadmium, copper, lead, nickel, zinc, chromium, and selenium.

(b) Final Limits. BPT limitations for this subcategory are now in effect (40 CFR 415.362). The BPT limitations are based on Option 2 technology, which is alkaline precipitation plus filtration. All the direct dischargers now have BPT technology.

The BPT regulations now in effect have different limitations for pure and impure raw material processes. In the final BPT limitations, we omit the separate limitations for pure raw material processes because both processes are adequately covered by the existing BPT limitations for impure raw material processes. Also, we did not set different limits for these processes in the promulgated BCT and BAT limitations and NSPS, PSES, and PSNS, since both processes are adequately covered by one regulation.

We are promulgating BAT limitations equal to BPT limitations because the cost of additional treatment is too high. Pollutants regulated under BAT limitations are copper, nickel, and selenium. We considered control Option 3 (sulfide precipitation), but rejected it because it removes only a small additional amount of toxic metals in this subcategory. We are promulgating BCT limitations that are equal to BPT limitations for the reasons described in Section V.B.4.(b) above.

We are promulgating NSPS equal to BPT/BAT limitations. Pollutants regulated under NSPS are TSS, copper, nickel, selenium, and pH.

PSES based on BPT technology are now in effect for this subcategory (40 CFR 415.374). In the final rule, however, we are amending the PSES limitations to make them equal to the BPT/BAT effluent concentrations for copper, nickel, and selenium. We are also promulgating PSNS that are equal to BPT/BAT limitations. Pretreatment standards are necessary because BPT/BAT provides better removal of copper, nickel, and selenium than is achieved by a well-operated POTW with secondary treatment installed, and, therefore, these pollutants would pass through a POTW in the absence of pretreatment.

Pollutants regulated under PSES and PSNS are copper, nickel, and selenium.

(c) Changes from Proposals. We have deleted limitations for all toxic metals except copper, nickel, and selenium because the technology necessary to

comply with the effluent limitations and standards established for copper, nickel, and selenium effectively controls the other toxic metals present in the untreated wastewater.

We proposed BAT limitations based on BPT technology, but with more stringent limitations because information indicated that the BPT technology performed better than had been indicated in our 1973-74 study, and therefore we believed the more stringent limitations could be met at no additional cost. However, industry comment stated that the more stringent limits would require additional treatment and therefore additional cost. We believe our treatability study shows that the more stringent limits can be met with existing treatment, but we have been unable to identify a copper sulfate plant treating copper sulfate wastewater separate from all other wastewaters that does meet the proposed BAT limits with existing treatment. Hence, considering the small daily volume of wastewater discharged from this industry, we have revised the proposed BAT limitations, and they are now equal to BPT. We have also revised the PSES, NSPS, and PSNS to equal BPT, for the same reason.

9. Nickel Sulfate (Subpart AU). (a) Background. This subcategory has 11 plants, 5 of which are direct dischargers and 6 are indirect dischargers.

Nickel sulfate is produced by reacting various forms of nickel with sulfuric acid. Two different types of raw materials are used to produce nickel sulfate. Pure nickel or nickel oxide powder may be used as a pure material source, while spent nickel catalysts, nickel plating solutions or residues are impure sources.

The process wastewater flow rate for a model plant that produces nickel sulfate is 0.68 m³/kkg. Plant wastewater sources include treated filter sludge and backwash. The toxic pollutants in this wastewater are antimony, arsenic, cadmium, chromium, copper, lead, mercury, nickel, selenium, thallium and zinc.

(b) Final Limits. BPT limitations for this subcategory are now in effect (40 CFR 415.472). The technology basis for the existing BPT limitations is Option 2 (alkaline precipitation plus dual-media filtration). All five direct discharge plants in this subcategory have installed BPT. Pollutants regulated under the existing BPT limitations are TSS, nickel, and pH.

In the existing BPT limitations, pure and impure raw material processes are regulated separately. In this final rule, the separate limitations for pure raw material are omitted, since both processes are adequately covered by

one regulation. We are also not setting different limits for these processes in BCT and BAT limitations and NSPS, PSES and PSNS.

We are promulgating BAT limitations and NSPS, PSES, and PSNS based on BPT technology, but the limitations are more stringent because additional data from this study show better performance than that on which the existing BPT limitations were based. The data base available when the existing BPT limitations were promulgated was extremely limited. Much more data is available now. All plants currently meeting BPT limitations can meet the BAT limitations with their existing treatment facilities, and therefore the more stringent BAT limitations do not require additional costs. Pretreatment standards are necessary because BAT provides better removal of copper and nickel than is achieved by a well-operated POTW with secondary treatment installed and, therefore, these pollutants would pass through a POTW in the absence of pretreatment. The pollutants regulated under the BAT limitation and PSES and PSNS are copper and nickel. Pollutants regulated under NSPS are the same with the addition of TSS and pH limits equal to those in the promulgated BPT regulations. We are promulgating BCT limitations that are equal to BPT limitations for the reasons described in Section V.B.4.(b) above.

We considered Option 3 (sulfide precipitation), but rejected it because the treatment removed only small additional amounts of nickel in this subcategory.

PSES that are based on BPT technology are now in effect (40 CFR 415.474). However, while the technology basis remains the same, we are amending the PSES limits to equal BAT. Again, only the performance requirements and not their technology basis are changed.

(c) Changes from Proposal. We have deleted limitations on all toxic metals except nickel and copper because the technology necessary to comply with the effluent limitations and standards established for nickel and copper effectively controls the other toxic metal pollutants present in the untreated wastewater. Based on new data from industry and our treatability study, we have revised the BAT limitations on copper and nickel; the limitation on copper is now more stringent while the limitation on nickel is now less stringent.

10. Sodium Bisulfite (Subpart BB). (a) Background. This subcategory has 7

plants, 6 of which are direct dischargers and 1 is an indirect discharger.

Sodium bisulfite is produced by reacting sodium carbonate (soda ash) with sulfur dioxide and water. This reaction produces a slurry of sodium bisulfite crystals, which can be sold, but which is usually processed to form anhydrous sodium metabisulfite. This process requires thickening, centrifuging, drying, and packaging.

The process wastewater flow rate for a model plant producing sodium bisulfite is 1.5 m³/kg. The principal wastewater sources are filter backwash and equipment washdown. The toxic pollutants in this wastewater are arsenic, copper, zinc, cadmium, chromium, lead, mercury, nickel, antimony, thallium, and silver.

(b) Final Limits. We are promulgating BPT limitations based on Option 1 plus Option 6, which include hydroxide precipitation of metals plus batch aeration and settling. The six direct dischargers in this subcategory have installed BPT technology. The basis for the limitations for TSS and COD is the *Treatability Study* (EPA 440/1-80/103). The basis for the limitations for zinc and chromium is industry data on wastewater treatment system performance. Pollutants regulated under BPT limitations are TSS, COD, chromium, zinc, and pH. We are promulgating BCT limitations that are equal to BPT limitations for the reasons described in Section V.B.4.(b) above.

We are promulgating BAT limitations, NSPS and PSNS equal to BPT limitations. Pollutants regulated under BAT limitations are COD, chromium and zinc. Pollutants regulated under NSPS are TSS, COD, chromium, zinc and pH. Pretreatment is necessary because NSPS treatment provides better removal of chromium than is achieved by a well-operated POTW, with secondary treatment installed, and, therefore, chromium would pass through a POTW in the absence of pretreatment. The pollutant regulated under PSNS is chromium. We are not promulgating categorical PSES or this subcategory for the reasons described below.

We considered adding treatment such as chlorination, sulfide precipitation, and filtration but rejected those options because of their high cost in removing additional toxic metals.

(c) Changes from Proposal. We have deleted limitations on all toxic metals except chromium and zinc because the technology necessary to comply with the effluent limitations and standards for chromium and zinc effectively controls the other toxic metal pollutants present in the untreated wastewater. Based on new industry data and the results of our

treatability study, we have revised the limitations on TSS, chromium, and zinc, and they are now less stringent. The COD limitations have also been adjusted slightly, based on the new data.

The proposed PSES and PSNS for the Sodium Bisulfite subcategory included limitations for COD and the toxic pollutants chromium, copper, lead, nickel, and zinc. In this final rule, we are promulgating PSNS that regulate only chromium, because only for chromium does BAT for this subcategory provide better removal than is achieved by a well-operated POTW with secondary treatment installed. Therefore, in the Sodium Bisulfite subcategory, only chromium would pass through a POTW in the absence of pretreatment. We are not promulgating PSES for this subcategory but instead are excluding the subcategory from categorical PSES under the provisions of paragraph 8(b) of the Settlement Agreement. The total toxic metal discharge from the one existing indirect discharger to POTW is 120 pounds per year, which is so insignificant as not to justify developing a national standard.

11. Sodium Hydrosulfite (Formate Process) (Subpart BE). We proposed BPT, BCT, and BAT limitations and NSPS, PSES, and PSNS for this subcategory. The proposed regulation basically added control of selected toxic metal pollutants to existing treatment practiced in the industry. We have reviewed the basis for the proposed regulation and we concluded that the total current treated discharge load of only 0.42 pounds per day total toxic metals from all plants in the subcategory is too insignificant to justify developing a national regulation. Accordingly, we have excluded this subcategory from national regulation development under Paragraph 8(a)(iv) of the Settlement Agreement.

VI. Costs and Economic Impacts

Executive Order 12291 requires EPA and other agencies to perform regulatory impact analyses of "major rules", defined as rules which impose an annual cost on the economy of \$100 million or more or meet other economic impact criteria. EPA does not consider this final regulation to be a major rule. This rulemaking satisfies the requirements of the Executive Order for a non-major rule.

The economic impact assessment is presented in *Economic Impact Analysis of Pollution Control Technologies For Segments of the Inorganic Chemicals Manufacturing Industry*, EPA 440/2-81-023. Copies of the analysis can be obtained by contacting the National

Technical Information Service, 5282 Port Royal Road, Springfield, VA 22161 (703/487-4600). The analysis details the investment and annual costs for the industry as a whole and for model plants in each subcategory covered by the regulation. The analysis also assesses the impact of effluent control costs in terms of price changes, profitability changes, plant closures, production changes, employment effects, and balance of trade effects. The analysis addresses the combined impact of the effluent limitations and the Interim Status Standards of the Resource Conservation and Recovery Act (RCRA-ISS) for segments of the industry that will incur both sets of compliance costs.

EPA has identified 144 plants that manufacture the chemicals covered by this regulation. Total investment for BPT, BAT and PSES is estimated to be \$28.9 million, with annualized costs of \$26.2 million (including depreciation and interest). These costs are expressed in 1981 dollars, and were updated from 1978 dollars using the Department of Commerce Composite Index for Construction Costs. A maximum of two potential production line closures are projected as a result of this regulation. In terms of unemployment, the potential line closures could affect approximately 60 employees—less than one percent of total employment for the regulated industry.

EPA evaluated the impacts of the pollution control costs for 13 segments of the inorganic chemicals industry using a model plant approach. The industry segments correspond to the product and, in some cases, the manufacturing process. Model plants were developed by product, process, and production size. The methodology involved calculating price and profitability impacts for each model plant. The profitability analysis assumes that the industry is unable to pass through any of the pollution control costs in the form of higher prices, and increased costs are fully absorbed. Changes in the return on investment (ROI) and internal rate of return (IRR) were calculated under this assumption. For each industry segment, plant or line closure projections were based on maximum possible price increase, profitability decline, capital availability, and other relevant factors. In summary, EPA concludes that the economic impacts of the additional water pollution controls likely to be incurred by this regulation are not significant and are justified in light of the benefits associated with compliance with the limitations and standards.

BPT/BAT: In five subcategories (Aluminum Fluoride, Copper Sulfate, Nickel Sulfate, Sodium Bisulfite, and Sodium Dichromate), and Titanium Dioxide-Chloride Process segment of the Titanium Dioxide subcategory, BAT technology is equivalent to BPT technology, and BPT is in place and operating for all direct dischargers. In the Titanium Dioxide-Chloride Ilmenite Process segment, all plants are achieving removal levels equivalent to BAT limitations. Thus, there will be no incremental costs over BPT required for compliance with BAT in five subcategories and two segments of a sixth subcategory. In the remaining four subcategories (Chlor-Alkali, Chrome Pigments, Hydrogen Cyanide, and Hydrogen Fluoride), and in the Titanium Dioxide-Sulfate Process segment of the Titanium Dioxide Subcategory, 77 plants will incur investment costs up to \$18.9 million and annualized costs up to \$18.6 million.

PSES: The total annualized costs of compliance with PSES limitations required for the 6 indirect dischargers not pretreating wastewater are approximately \$7.6 million. Total investment costs are approximately \$9.9 million. These costs affect two subcategories (Chlor-Alkali Diaphragm Cell and Chrome Pigments). In only the Chrome Pigments subcategory, discussed below, will profitability decline significantly.

NSPS/PSNS: Regulations for new sources are not expected to significantly discourage entry or result in any differential economic impacts on new plants. The pollution control investment required to install a treatment technology is the same for new and existing producers in the industry. Therefore, new plants will not be operating at a cost disadvantage relative to current manufacturers.

Chrome Pigments: For this subcategory, BPT, BCT, BAT, and PSES limitations are the same. Four of the twelve plants producing chrome pigments are direct dischargers and are subject to BPT/BAT regulations. Two of the direct dischargers have sufficient pollution control technology installed and will incur no incremental costs for compliance with BAT regulations. The other two direct dischargers will incur capital investment costs of \$1.9 million with total annualized costs of \$1.1 million, but our analysis indicates that both plants will continue production of chrome pigments at those plants.

Under the proposed regulations, all eight indirect dischargers would have been subject to the categorical pretreatment standards. However, we are now excluding from compliance with

categorical PSES existing plants that discharge less than 210,000 m³ per year of chrome pigments process wastewater to POTWs. (General pretreatment standards remain applicable). This exclusion effectively applies to small indirect dischargers producing less than 2,000 kkg per year of chrome pigments and is necessary in order to avoid excessive economic impacts on this segment of the industry. Without the exclusion, the analysis of compliance costs for this subcategory indicates significant financial impacts for these smaller plants. The estimated price increase needed to recover pollution control costs for the smallest model plant is 14.0 percent. The profitability decline for this model exceeds 100 percent of baseline profitability. Plants corresponding to the small model plant are the least profitable and are currently operating at marginal levels. Another significant factor for these small manufacturers is the potential difficulty of securing the capital needed to invest in pollution control equipment.

Three plants, which were predicted to close under the proposed regulation, will not be subject to PSES. These three plants, if they were subject to PSES, would have incurred capital investment costs of \$2.1 million and annualized costs of \$0.9 million. The remaining five indirect dischargers are subject to pretreatment standards. Capital investment costs for the five indirect dischargers incurring costs are approximately \$8.7 million, with total annualized costs of \$6.8 million.

Two of the five indirect dischargers who will be subject to the regulations are medium-sized plants discharging more than 210,000 m³ per year to POTWs. These two plants may decide to close their chrome pigments production operations rather than construct wastewater treatment facilities to comply with the PSES. If so, up to 60 employees could be affected. However, at both of these plants, chrome pigments production accounts for less than 10 percent of the total facility production. Therefore, it is probable that the 60 employees could be transferred to other production operations at the facilities, with no increase in unemployment.

The Agency was unable to identify any technologies less costly than the one chosen which would remove significant amounts of toxic pollutants. The small plant cut-off was the only option available to avoid the severe economic impact on the three small producers.

Regulatory Flexibility Analysis: Public Law 96-354 requires that a Regulatory Flexibility Analysis (RFA) be

prepared for regulations proposed after January 1, 1981 that have a significant impact on a substantial number of small entities. Although this regulation was proposed in July 1980, an RFA is included as part of the economic impact analysis. Many of the provisions of the RFA have been addressed in detail in other sections of this preamble.

The economic impact analysis (discussed above) outlines the costs and economic impacts for each subcategory covered by the regulation. The small entities in each subcategory were defined as those plants corresponding to the small model plant size, which represents small plant production levels within each subcategory. Sixty-nine plants covered by the regulations were identified as small. The possible impacts on small plants and the alternatives the Agency considered are discussed above and in the economic analysis.

VII. Non-Water-Quality Environmental Impacts

Eliminating or reducing one form of pollution may cause other environmental problems. Sections 304(b) and 306 of the Act require EPA to consider the non-water-quality environmental impacts (including energy requirements) of certain regulations. In compliance with these provisions, we considered the effect of this regulation on air pollution, solid waste generation, water scarcity, and energy consumption. This regulation was circulated to and reviewed by EPA personnel responsible for non-water-quality programs. While it is difficult to balance pollution problems against each other and against energy use, we believe that this regulation will best serve often competing national goals.

The following non-water-quality environmental impacts (including energy requirements) are associated with the final regulation. The Administrator has determined that the impacts identified below are justified by the benefits associated with compliance with the limitations and standards.

A. Air Pollution

Imposition of BPT and BAT limitations and NSPS, PSES, and PSNS will not create any substantial air pollution problems. Some acid vapor and dust releases may occur as a result of proposed NSPS for the Hydrofluoric Acid subcategory. These can be prevented with available technology. We included the cost of this technology in the cost analysis.

B. Solid Waste

A substantial amount of solid waste has been generated under the existing limitations and standards. The largest amount of solid waste is generated by BPT treatment. Less than 500 pounds per day (dry basis) will be produced by implementation of BAT limitations and PSES and PSNS. The largest amount of solid waste will come from the implementation of BPT for the Titanium Dioxide subcategory. Plants in this subcategory will generate 4,720 tons per day of solid wastes, compared with approximately 900 tons/day for existing BPT limitations in other subcategories. A process has been developed for converting the solid wastes (gypsum) from the titanium dioxide (sulfate process) to a useful product and one plant has developed a market for the solid waste.

Regulations recently promulgated by EPA under Section 3001 of the Resource Conservation and Recovery Act (RCRA) list as hazardous a number of solid wastes resulting from the production of inorganic chemicals. These include wastes from the Chrome Pigments subcategory (40 CFR Part 26, 45 FR 33084 (May 19, 1980)) and the Chlor-Alkali subcategory (45 FR 47832 (July 16, 1980)). Other inorganic chemical wastes may be hazardous because they exhibit one or more of EPA's hazardous characteristics identified in 40 CFR Part 261. If a waste is identified or listed as hazardous, it is subject to handling, transportation, treatment, storage, and disposal requirements under Sections 3002-3005 of RCRA and EPA regulations promulgated under RCRA. See 40 CFR Parts 261-267.

Compliance with these requirements involves costs in addition to the costs for compliance with the effluent limitations established by this regulation. The specific standards necessary to estimate these costs have been established, and costs for compliance with RCRA-ISS requirements are specifically considered in the economic impact analysis for this regulation.

C. Consumptive Water Loss

Treatment and control technologies that require extensive recycling and reuse of water may require cooling mechanisms. Evaporative cooling mechanisms can cause water loss and contribute to water scarcity problems—a primary concern in arid and semi-arid regions. This regulation assumes some recycling, thus assuming some cooling mechanisms may be required which could create additional consumptive water loss. However, the quantity of

water involved is not significant, and most of the industry is located in coastal areas or areas with sufficient water resources. Moreover, we concluded that the pollution reduction benefits of recycle technologies outweigh their impact on consumptive water loss.

D. Energy Requirements

We estimate that the achievement of BPT effluent limitations and PSES will increase electrical energy consumption by approximately 410 million kilowatt-hours per year. Implementing BAT limitations will consume another 2 million kilowatt-hours. Achievement of BPT and BAT effluent limitations will require a typical direct discharger to increase total energy consumption by less than one percent of the energy now consumed in production purposes.

VIII. Pollutants and Subcategories Not Regulated

The Settlement Agreement contains provisions authorizing the exclusion from regulation, in certain circumstances, of toxic pollutants and industry categories and subcategories. These provisions have been rewritten in a Revised Settlement Agreement which was approved by the District Court for the District of Columbia on March 9, 1979, 12 ERC 1833.

A. Exclusion of Pollutants

Paragraph 8(a)(iii) of the Settlement Agreement authorizes the Administrator to exclude the following toxic pollutants from regulation: (a) Those not detectable by Section 304(h) analytical methods or other state-of-the-art methods; (b) those present in amounts too small to be effectively reduced by available technologies; (c) those present only in trace amounts and neither causing nor likely to cause toxic effects; (d) those detected in the effluent from only a small number of sources within a subcategory and uniquely related to those sources; and (e) those that will be effectively controlled by the technologies on which other effluent limitations and standards are based. The toxic pollutants excluded from regulation in all subcategories, under paragraph 8(a)(iii) of the Settlement Agreement, are listed in Appendix B of this Notice.

We are also excluding certain toxic pollutants from particular subcategories. Since the date of the proposed regulation (July 24, 1980), we excluded additional pollutants from particular subcategories under paragraph 8(a)(iii) of the Settlement Agreement. Justification for these additional exclusions is based on the review of more reliable industry data and the

results of treatability studies showing that these pollutants will be effectively controlled by the technologies on which other effluent limitations and standards are based. These pollutants and the reason for their exclusion under paragraph 8(a)(iii) are listed in Appendix C of this Notice.

In addition to the pollutants excluded under the Settlement Agreement, we are excluding asbestos from this regulation at this time because no standardized 304(h) analytical method for asbestos in water is available.

B. Exclusion of Subcategories

Paragraph 8(a)(i) of the Settlement Agreement authorizes the Administrator to exclude from regulation industry categories or subcategories for which equal or more stringent limitations are already provided by existing effluent limitations and standards. Also, paragraph 8(a)(iv) of the Settlement Agreement authorizes the exclusion of subcategories in which the amount and toxicity of each pollutant in the discharge does not justify developing national regulations.

Paragraph 8(b) of the Settlement Agreement authorizes the Administrator to exclude from regulation under the pretreatment standards a subcategory if (i) 95 percent or more of all point sources in the subcategory introduce into POTWs only pollutants which are susceptible to treatment by the POTW and which do not interfere with, do not pass through, or are not otherwise incompatible with such treatment works; or (ii) the toxicity and amount of the incompatible pollutants introduced by such point sources into POTWs is so insignificant as not to justify developing a pretreatment regulation. The subcategories excluded under paragraphs 8(a)(1), 8(a)(iv), and 8(b) of the Settlement Agreement are listed in Appendix D of this Notice.

In addition to the subcategories excluded under the Settlement Agreement, many subcategories of the Inorganic Chemicals Manufacturing Point Source Category are being deferred. The subcategories under Phase II of the Inorganic Chemicals Manufacturing Point Source Category are listed in Appendix E of this notice. The phase I regulation promulgated today covers 85 percent of the discharges containing toxic pollutants from the Inorganic Chemicals Industry.

IX. Responses to Major Comments

In this section, we will respond to those issues raised in a large number of the comments received and affecting essentially all subcategories. A

summary of the comments received and our detailed responses to all comments are included in a report "Responses to Public Comments, Proposed Inorganic Chemicals Manufacturing Effluent Guidelines and Standards", which is a part of the public record for this regulation.

A. Toxic Metals To Be Limited In Final Regulation

In the proposed regulations toxic metals selected for proposed limitations included all those for which the maximum concentration observed in screening or verification sampling was above the level of treatability. Many commenters recommended the limitation of only one or two of the dominant toxic metals because this will control all other toxic metals and reduce analytical cost. We agree with this comment. Chemical treatment for removal of a metal from a waste stream will also affect and remove all metals in that waste stream with a different percent removal for individual metals. The design, construction and operation of a wastewater treatment system to preferentially remove a single metal from a wastewater stream which contains several metals is just not feasible. Since the source of metals in this industry is primarily the ore, it is not possible to bypass the regulations by substituting a metal that is not limited for one that is limited.

Accordingly, since the date of proposal we excluded additional pollutants from particular subcategories under paragraph 8(a)(iii) of the Settlement Agreement. The pollutants are present in the untreated wastewater at relatively low concentrations and, as demonstrated by review of industry data and the treatability study, will be effectively controlled by the technology necessary to comply with the effluent limitations and standards established for the pollutants present in untreated wastewater at high concentrations. These pollutants are listed in Appendix C of this notice.

B. Numerical Values of Specific Toxic Metal Pollutant Limitations

In the proposed regulations many of the specific toxic metal pollutant limitations were derived from literature data, and the lower end of the range of literature values was generally selected as the maximum thirty-day average limitation. Many commenters stated that the lower end of the range of literature values was not representative of the maximum thirty-day average performance expected from a treatment facility, and provided additional data for our consideration.

We agree with this comment, and are very appreciative of the additional data provided, which has greatly expanded the data base available. Based on this new data, and the results of our treatability study, we have changed many of the numerical values of specific pollutant limitations in this final rule. In general, they are now less stringent. The new data has led to more accurate numerical averages, and more accurate variability factors for use in establishing limitations.

X. Best Management Practices

Section 304(e) of the Clean Water Act gives the Administrator authority to prescribe "best management practices" (BMPs). EPA intends to develop BMPs that are (a) applicable to all industrial sites; (b) applicable to a designated industrial category; and (c) offer guidance to permit authorities in establishing BMPs required by unique circumstances for a given plant.

Although EPA is not proposing them at this time, we are considering development of BMPs specific to the Inorganic Chemicals Industry. The industry has numerous problem areas including leaks and spills, storm water runoff, and groundwater infiltration from storage areas and on-site solid waste disposal. Most subcategories have problems in some or all of these areas. Sections 11-25 of the development document describe possible BMPs for each regulated subcategory. This information can guide the permitting agency in developing case-by-case BMPs for NPDES permits.

Future BMPs may require dikes, curbs, or other measures to contain leaks and spills, as well as the treatment of toxic pollutants in these wastes.

XI. Upset and Bypass Provisions

A recurring issue of concern has been whether industry guidelines should include provisions authorizing noncompliance with effluent limitations during periods of "upset" or "bypass." An upset, sometimes called an "excursion", is an unintentional noncompliance occurring for reasons beyond the reasonable control of the permittee. It has been argued that an upset provision in EPA's effluent limitations is necessary because such upsets will inevitably occur even in properly operated control equipment. Because technology based limitations require only what technology can achieve, it is claimed that liability for such situations is improper. When confronted with this issue, courts have disagreed on whether an explicit upset or excursion exemption is necessary, or whether upset or excursion incidents

may be handled through EPA's exercise of enforcement discretion. Compare *Marathon Oil Co. v. EPA*, 564 F. 2d 1253 (9th Cir. 1977) with *Weyerhaeuser v. Costle, supra*, and *Corn Refiners Association, et al. v. Costle*, No. 78-1069 (8th Cir., April 2, 1979). See also *American Petroleum Institute v. EPA*, 540 F. 2d 1023 (10th Cir. 1976); *CPC International, Inc. v. Train*, 540 F. 2d 1320 (8th Cir. 1976); *FMC Corp. v. Train*, 539 F. 2d 973 (4th Cir. 1976).

An upset is an unintentional episode during which effluent limits are exceeded; a bypass however, is an act of intentional noncompliance during which waste treatment facilities are circumvented in emergency situations. We have, in the past, included bypass provisions in NPDES permits.

We determined that both upset the bypass provisions should be included in NPDES permits and have promulgated Consolidated Permit regulations that include upset and bypass permit provisions (See 40 CFR 122.60, 45 FR 33290 (May 19, 1980)). The upset provision establishes an upset as an affirmative defense to prosecution for violation of technology-based effluent limitations. The bypass provision authorizes bypassing to prevent loss of life, personal injury, or severe property damage. Consequently, although permittees in the Inorganic Chemicals Industry will be entitled to upset and bypass provisions in NPDES permits, this final regulation does not address these issues.

XII. Variances and Modifications

Upon the promulgation of this regulation, the effluent limitations for the appropriate subcategory must be applied in all Federal and State NPDES permits thereafter issued to direct dischargers in the Inorganic Chemicals Industry. In addition, on promulgation, the pretreatment limitations are directly applicable to any indirect dischargers.

For the BPT effluent limitations, the only exception to the binding limitations is EPA's "fundamentally different factors" variance. See *E. I. du Pont de Nemours & Co. v. Train*, 430 U.S. 112 (1977); *Weyerhaeuser Co. v. Costle, supra*. This variance recognizes factors concerning a particular discharger that are fundamentally different from the factors considered in this rulemaking. Although this variance clause was set forth in EPA's 1973-76 industry regulations, it is now included in the NPDES regulations and will not be included in the inorganic chemicals or other industry regulations. See the NPDES regulations at 40 CFR Part 125, Subpart D.

The BAT limitations in this regulation are also subject to EPA's "fundamentally different factors" variance. BAT limitations for nonconventional pollutants are subject to modifications under Sections 301(c) and 301(g) of the Act. These statutory modifications do not apply to toxic or conventional pollutants. According to Section 301(j)(1)(B), applications for these modifications must be filed within 270 days after promulgation of final effluent limitations guidelines.

The economic modification section (301(c)) gives the Administrator authority to modify BAT requirements for nonconventional pollutants (Section 301(1) precludes the Administrator from modifying BAT requirements for any pollutants which are on the toxic pollutant list under section 307(a)(1) of the Act) for dischargers who file a permit application after July 1, 1977, upon a showing that such modified requirements will (1) represent the maximum use of technology within the economic capability of the owner or operator and (2) result in reasonable further progress toward the elimination of the discharge of pollutants. The environmental modification section (301(g)) allows the Administrator, with the concurrence of the State, to modify BAT limitations for nonconventional pollutants from any point source upon a showing by the owner or operator of such point source satisfactory to the Administrator that:

(a) Such modified requirements will result at a minimum in compliance with BPT limitations or any more stringent limitations necessary to meet water quality standards;

(b) such modified requirements will not result in any additional requirements on any other point or non-point source; and

(c) such modification will not interfere with the attainment or maintenance of that water quality which shall assure protection of public water supplies, and the protection and propagation of a balanced population of shellfish, fish, and wildlife, and allow recreational activities, in and on the water and such modification will not result in the discharge of pollutants in quantities which may reasonably be anticipated to pose an unacceptable risk to human health or the environment because of bioaccumulation, persistency in the environment, acute toxicity, chronic toxicity (including carcinogenicity, mutagenicity or teratogenicity), or synergistic propensities.

Section 301(j)(1)(B) of the Act requires that application for modifications under section 301 (c) or (g) must be filed within 270 days after the promulgation of an

applicable effluent guideline. Initial applications must be filed with the Regional Administrator and, in those States that participate in the NPDES program, a copy must be sent to the Director of the State program. Initial applications to comply with 301(j) must include the name of the permittee, the permit and outfall number, the applicable effluent guideline, and whether the permittee is applying for the 301(c) or 301(g) modification or both. Applicants interested in applying for both must do so in their initial application. For further details, see 43 FR 40859, September 13, 1978.

The nonconventional pollutants limited under BAT in this regulation are chemical oxygen demand (COD), fluoride, and residual chlorine. No regulations establishing criteria for 301(c) and 301(g) determinations have been proposed or promulgated, but the Agency recently announced in the April 12, 1982 Regulatory Agenda plans to propose such regulations by December, 1982 (47 FR 15702). All dischargers who file an initial application within 270 days will be sent a copy of the substantive requirements for 301(c) and 301(g) determinations once they are promulgated. Modification determinations will be considered at the time the NPDES permit is being reissued. Pretreatment standards for existing sources are subject to the "fundamentally different factors" variance and credits for pollutants removed by POTW. (See 40 CFR 403.7, 403.13; 43 FR 27736 [June 26, 1978]).

Pretreatment standards for new sources are subject only to the credits provision in 40 CFR 403.7. NSPS are not subject to EPA's "fundamentally different factors" variance or any statutory or regulatory modifications. See *E. I. du Pont de Nemours and Co. v. Train*, supra.

XIII. Relationship to NPDES Permits

The BPT limitations and NSPS in this regulation will be applied to individual inorganic chemicals manufacturers through NPDES permits issued by EPA or approved state agencies, under Section 402 of the Act. As discussed in the preceding section of this preamble, these limitations must be applied in all Federal and State NPDES permits except to the extent that variances and modifications are expressly authorized. Other aspects of the interaction between these limitations and NPDES permits are discussed below.

One issue that warrants consideration is the effect of this regulation on the powers of NPDES permit-issuing authorities. The promulgation of this regulation does not restrict the power of

any permitting authority to act in any manner consistent with law or these or any other EPA regulations, guidelines, or policy. For example, even if this regulation does not control a particular pollutant, the permit issuer may still limit such pollutant on a case-by-case basis when limitations are necessary to carry out the purposes of the Act. In addition, to the extent that State water quality standards or other provisions of State or Federal law require limitation of pollutants not covered by this regulation (or require more stringent limitations on covered pollutants), such limitations must be applied by the permit-issuing authority.

A second topic that warrants discussion is the operation of EPA's NPDES enforcement program, many aspects of which were considered in developing this regulation. We emphasize that although the Clean Water Act is a strict liability statute, the initiation of enforcement proceedings by EPA is discretionary. We have exercised and intend to exercise that discretion in a manner that recognizes and promotes good-faith compliance efforts and conserves enforcement resources for those who fail to make good-faith efforts to comply with the Act.

XIV. Public Participation

Numerous agencies and groups have participated during the development of these effluent guidelines and standards. Following the publication of the proposed rules on July 24, 1980 in the Federal Register, we provided the development document supporting the proposed rules to industry, Government agencies, and the public sector for comments. Two workshops were held on the Inorganic Chemicals BAT Rulemaking in Philadelphia, PA, and Dallas, TX, on October 7, and October 9, 1980, respectively. On October 15, 1980, in Washington, D.C., a public hearing was held on the proposed pretreatment standards.

The following organizations responded with comments: The Chlorine Institute, Inc.; N.L. Industries; Freeport Minerals Company; Virginia Chemicals, Inc.; Olin Chemicals Inc.; PPG Industries; Office of the President, Council on Wage and Price Stability; Dow Chemical U.S.A.; Chemical Manufacturers Association; Gulf and Western; U.S. Department of Commerce, General Council; Rohm & Haas Company; Allied Chemical Corporation; Kaiser Aluminum and Chemical Corporation; Brunswick Pulp & Paper Company; Diamond Shamrock; Texas Department of Water Resources; South Carolina Department of Health and

Environmental Control; Weyerhaeuser Company; American Cyanamid Company; New York State Department of Environmental Conservation; Hooker Chemicals and Plastics Corporation; Babcock & Wilcox; Vulcan Materials Company; Georgia Pacific Corporation; E.I. du Pont de Nemours & Company; Pennwalt Corporation; FMC Corporation; Monsanto Corporation; Hamilton Standard; Linden Chemicals and Plastics, Inc.; and SCM Chemical/Metallurgical Division.

Fifty-four letters with comments have been received. These letters included 27 addressing the Chlor-Alkali subcategory, 12 addressing Titanium Dioxide, 3 addressing Hydrofluoric Acid, 2 each addressing Hydrogen Cyanide, Chrome Pigments, Aluminum Fluoride, Copper Sulfate, and Sodium Bisulfite, and 1 each addressing Sodium Hydrosulfite, and Sodium Dichromate. Seven letters addressed general topics only. Several letters addressed multiple topics. Nine letters contained effluent data and 2 contained economic data. Eight of the 11 subcategories for which limitations and standards were proposed received 2 or fewer comment letters.

All comments received have been carefully considered, and appropriate changes in the regulation have been made whenever available data and information supported those changes. Major issues raised by the comments are addressed under the relevant section within the body of this preamble. A summary of the comments received and our detailed responses to all comments are included in a report "Responses to Public Comments, Proposed Inorganic Chemical Manufacturing Effluent Guidelines and Standards," which is a part of the public record for this regulation. This report, along with the rest of the public record, will be available for public review three weeks after the effective date in EPA's Public Information Reference Unit, Room 2004 (Rear), (EPA Library), 401 M Street, SW., Washington, D.C.

XV. Small Business Administration (SBA) Financial Assistance

The Agency is continuing to encourage small manufacturers to use Small Business Administration (SBA) financing as needed for pollution control equipment. Three basic programs are in effect: the Guaranteed Pollution Control Bond Program, the Section 503 Program, and the Regular Guarantee Program. All the SBA loan programs are only open to businesses with net assets less than \$6 million, with an average annual after-tax income of less than \$2 million, and with fewer than 250 employees.

The guaranteed pollution control bond is a full faith and credit instrument with a tax free feature, making it the most favorable of the programs. Although all 1981 funds have already been committed, the SBA is attempting to obtain additional funding for this program. The program applies to projects that cost from \$150,000 to \$2,000,000.

The Section 503 Program, as amended in July 1980, allows for long-term loans to small and medium-sized businesses. These loans are made by SBA-approved local development companies, which for the first time are authorized to issue Government-backed debentures that are bought by the Federal Financing Bank, an arm of the U.S. Treasury.

Though SBA's Regular Guarantee Program, loans are made available by commercial banks and are guaranteed by the SBA. This program has interest rates equivalent to market rates.

For additional information on the Regular Guarantee and Section 503 Programs contact your district or local SBA Office. The coordinator at EPA headquarters is Ms. Frances Desselle who may be reached at (202) 426-7874.

For further information and specifics on the Guaranteed Pollution Control Bond Program contact: U.S. Small Business Administration, Office of Pollution Control Financing, 4040 North Fairfax Drive, Rosslyn, Virginia 22203, (703) 235-2902.

The regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Dated: June 16, 1982.

Anne M. Gorsuch,
Administrator.

XVI. Availability of Technical Information

The basis for this regulation is detailed in four major documents. Analytical methods are discussed in *Sampling and Analysis Procedures for Screening of Industrial Effluents for Priority Pollutants*. EPA's technical conclusions are detailed in *Development Document for Effluent Guidelines, New Source Performance Standards and Pretreatment Standards for the Inorganic Chemicals Manufacturing Point Source Category* EPA 440/1-82-007. The Agency's economic analysis is presented in *Economic Impact Analysis of Pollution Control Technologies for Segments of the Inorganic Chemicals Manufacturing Industry*, EPA 440/2-81-023. A contractor's report on treatability studies is presented in *Treatability Studies for the Inorganic Chemical Manufacturing Point Source Category*

(EPA 440/1-80/103). A summary of the public comments received on the proposed regulation is presented in a report "Responses to Public Comments, Proposed Inorganic Chemicals Manufacturing Effluent Guidelines and Standards", which is a part of the public record for this regulation.

Technical information may be obtained by writing to Dr. Thomas E. Fielding, Effluent Guidelines Division (WH-552), EPA, 401 M Street, SW., Washington, D.C. 20460, or through calling (202) 426-2582. Copies of the technical documents may be obtained from the National Technical Information Service, Springfield, Virginia 22161 (703/487-6000). The economic analysis may also be obtained from the National Technical Information Service.

The Record will be available for public review three weeks after the effective date in EPA's Public Information Reference Unit, Room 2004 (Rear) (EPA Library), 401 M Street, SW., Washington, D.C. The EPA information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

XVII. Appendixes

Appendix A—Abbreviations, Acronyms, and Other Terms Used in This Notice

- Act—The Clean Water Act
- Agency—The U.S. Environmental Protection Agency
- BAT—The best available technology economically achievable under Section 304(b)(2)(B) of the Act
- BCT—The best conventional pollutant control technology, under Section 304(b)(4) of the Act
- BMPs—Best management practices under Section 304(e) of the Act
- BPT—The best practicable control technology currently available under Section 304(b)(1) of the Act
- Clean Water Act—The Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. 1251 *et seq.*), as amended by the Clean Water Act of 1977 (Public Law 95-217)
- Direct discharger—A facility which discharges or may discharge pollutants into waters of the United States
- Indirect discharger—A facility which discharges or may discharge pollutants into a publicly owned treatment works
- NPDES permit—A National Pollutant Discharge Elimination System permit issued under Section 402 of the Act
- NSPS—New source performance standards under Section 306 of the Act
- POTW—Publicly owned treatment works
- PSIS—Pretreatment standards for existing sources of indirect discharges under Section 307(b) of the Act
- PSNS—Pretreatment standards for new sources of indirect discharges under Section 307(b) and (c) of the Act

RCRA—Resource Conservation and Recovery Act (Public Law 94-580) of 1976, Amendments to Solid Waste Disposal Act

Appendix B—Toxic Pollutants Excluded in All Subcategories

(1) Toxic Pollutants Not Detected in Wastewaters:

Acenaphthene
Acrolein
Acrylonitrile
Benzidine
1,2,4-Trichlorobenzene
Hexachlorobenzene
1,1-Dichloroethane
Chloroethane
Bis(2-chloroethyl) ether
2-Chloroethyl vinyl ether (mixed)
2-Chloronaphthalene
2,4,6-Trichlorophenol
Parachlorometa cresol
2-Chlorophenol
1,3-Dichlorobenzene
1,4-Dichlorobenzene
3,3-Dichlorobenzidine
1,2-Trans-dichloroethylene
2,4-Dichlorophenol
1,2-Dichloropropane
2,4-Dimethylphenol
2,4-Dinitrotoluene
1,2-Diphenylhydrazine
4-Chlorophenyl phenyl ether
4-Bromophenyl phenyl ether
Bis(2-Chloroethoxy) methane
Methyl chloride (chloromethane)
Methyl bromide (bromomethane)
Bromoform (tribromomethane)
Hexachlorobutadiene
Hexachlorocyclopentadiene
Isophorone
2-Nitrophenol
4,6-Dinitro-o-cresol
N-nitrosodimethylamine
N-nitrosodiphenylamine
N-nitrosodi-n-propylamine
Di-n-octyl phthalate
Benzo(k)fluoranthene (11,12-benzo-fluoroanthene)
Acenaphthylene
Benzo(ghi)perylene(1,12-benzoperylene)
Dibenzo(a,h)anthracene(1,2,5,6-dibenzanthracene)
Indeno(1,2,3-cd)pyrene(2,3-o-phenylenepyrene)
Vinyl chloride (chloroethylene)
Aldrin
Dieldrin
Chlordane (technical mixture & metabolites)
4,4'-DDT
4,4'-DDE (p,p'-DDX)
4,4'-DDD (p,p'-TDE)
A-endosulfan-Alpha
B-endosulfan-Beta
Endosulfan sulfate
Endrin
Endrin aldehyde
Heptachlor
Heptachlor epoxide
Hexachlorocyclohexane
A-BHC-Alpha
B-BHC-Beta
R-BHC-(lindane)-Gamma
G-BHC-Delta
PCB-1242 (Arochlor 1242)
PCB-1254 (Arochlor 1254)
PCB-1221 (Arochlor 1221)

PCB-1232 (Arochlor 1232)

PCB-1248 (Arochlor 1248)

PCB-1016 (Arochlor 1016)

Toxaphene

Note.—2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) was not measured because of the hazard in laboratory analysis associated with handling TCDD standards.

(2) Toxic Pollutants in Effluents Below the Level of Treatability:

Benzene—Present in one case at a higher level only in a raw waste, not in the BPT effluent
Carbon Tetrachloride
Chlorobenzene
1,2-Dichloroethane
1,1,1-Trichloroethane—Present in one case at a higher level only in a raw waste, not in the BPT effluent
Hexachloroethane
1,1,2-Trichloroethane
Chloroform—Present in three cases at higher levels only in raw wastes, not in the BPT effluents
1,1,2,2-Tetrachloroethane
1,2-Dichlorobenzene
1,1-Dichloroethylene
2,6-Dinitrotoluene
Ethylbenzene—Present in one case at a higher level only in a raw waste, not in the BPT effluent
Fluoroethane
Bis(2-chloroisopropyl) ether
Methylene chloride—Present in four cases at higher levels only in raw wastes, not in the BPT effluents
Dichlorobromomethane
Chlorodibromomethane
Naphthalene—Present in one case at a higher level only in raw waste, not in the BPT effluent
Nitrophenol
Phenol
Bis(2-Ethylhexyl phthalate)
Butyl benzyl phthalate
Di-n-butyl phthalate
Diethyl phthalate
Benzo(a) anthracene
Benzo(a) pyrene
3,4-Benzofluoroethane
Chrysene
Anthracene
Fluorene
Phenanthrene
Pyrene
Tetrachloroethylene
Toluene—Present in one case at a higher level only in raw waste, not in the BPT effluent
Trichloroethylene
Thallium
Beryllium
Antimony
Arsenic
Cadmium
Silver

(3) Toxic Pollutants Found in One or Two Plants Where Such Pollutants Are Unique to These Plants:

Nitrobenzene—Present at a single plant as a result of organic products manufactured on the plant site
2,4-Nitrophenol—Present at a single site as a result of organic products manufactured on the plant site

Dichloropropylene—Present at one plant site in the raw waste at the treatability level but not in the treated effluent

Pentachlorophenol—Present at one plant where it was used as a weed killer near a waste treatment lagoon. This practice was discontinued as a result of this finding

Appendix C—Toxic Pollutants Excluded in Particular Subcategories

Under Paragraph 8(a)(iii) of the Settlement Agreement, EPA is excluding certain toxic pollutants from regulation in particular subcategories, for one or all of the following reasons:

(a) The pollutant is not detectable in the effluent with the use of analytical methods approved pursuant to 304(h) of the Act or other state of the art methods.

(b) The pollutant is present only in trace amounts and is neither causing nor likely to cause toxic effects.

(c) The pollutant is present in amounts too small to be effectively reduced by technologies known to the Administrator.

(d) The pollutant will be effectively controlled by the technologies upon which are based other effluent limitations and guidelines, standards of performance or pretreatment standards.

The reason(s) for each of the following exclusions is keyed to the above list.

Chlor-Alkali Subcategory (Subpart F)

Antimony-c	Cyanide-a
Arsenic-d	Selenium-a
Cadmium-d	Silver-d
Chromium-d	

The pollutants limited are mercury at mercury cell plants, and copper, lead, and nickel at diaphragm cell plants.

Hydrofluoric Acid Subcategory (Subpart H)

Antimony-d	Cyanide-a
Arsenic-c,d	Lead-d
Cadmium-a	Mercury-d
Chromium-d	Selenium-a
Copper-d	Silver-a

The pollutants limited are nickel and zinc.

Titanium Dioxide Subcategory (Subpart V)

Antimony-d	Mercury-a
Arsenic-d	Selenium-a
Cadmium-d	Silver-a
Copper-d	Zinc-d
Lead-d	

The pollutants limited are chromium and nickel.

Aluminum Fluoride Subcategory

(Subpart W)

Antimony-c	Lead-d
Arsenic-c,d	Mercury-c
Cadmium-c	Selenium-c
Copper-c,d	Silver-a
Cyanide-a	Zinc-c

The pollutants limited are chromium and nickel.

Chrome Pigments Subcategory (Subpart AH)

Antimony-d	Mercury-d
Arsenic-a	Nickel-d
Cadmium-d	Selenium-a
Copper-d	Silver-a

The pollutants limited are chromium lead and zinc.

Hydrogen Cyanide Subcategory**(Subpart AP)**

Antimony-a	Lead-a
Arsenic-a	Mercury-a
Cadmium-a	Selenium-a
Chromium-a	Silver-a
Copper-a	

The only toxic pollutant found at significant levels in this subcategory was cyanide.

Sodium Dichromate Subcategory (Subpart Q)

Antimony-a	Lead-a
Arsenic-a	Mercury-a
Cadmium-a	Selenium-a
Copper-c,d	Silver-a
Cyanide-a	Zinc-d

The pollutants limited are chromium and nickel.

Copper Sulfate Subcategory (Subpart AJ)

Antimony-d	Lead-d
Arsenic-d	Mercury-a
Cadmium-d	Silver-a
Chromium-d	Zinc-d
Cyanide-a	

The pollutants limited are copper, nickel, and selenium.

Nickel Sulfate Subcategory (Subpart AU)

Antimony-d	Lead-d
Arsenic-c	Mercury-a
Cadmium-d	Selenium-c
Chromium-d	Silver-a
Cyanide-a	Zinc-d

The pollutants limited are copper and nickel.

Sodium Bisulfite Subcategory (Subpart BB)

Antimony-c	Lead-d
Arsenic-c	Mercury-c
Cadmium-d	Nickel-d
Copper-d	Selenium-a
Cyanide-a	Silver-a

The pollutants limited are chromium and zinc.

Appendix D—Subcategories Excluded

The following subcategories are excluded under Paragraph 8(a)(i) of the Settlement Agreement because existing BPT or BAT limitations prohibit discharge of process wastewater pollutants for direct dischargers in these subcategories.

Bromine (Subpart AC)
Calcium Oxide (Subpart E)
Chromic Acid (Subpart AI)
Calcium Hydroxide (Subpart AE)
Fluorine (Subpart AN)
Hydrogen (Subpart AO)
Iodine (Subpart AQ)
Potassium Chloride (Subpart AX)
Stannic Oxide (Subpart BH)
Zinc Sulfate (Subpart BK)
Calcium Carbide (Subpart C)
Potassium Metal (Subpart K)
Sodium Bicarbonate (Subpart N)
Borax (Subpart AA)
Ferric Chloride (Subpart AL)
Lead Monoxide (Subpart AR)
Sodium Fluoride (Subpart BC)
Potassium Sulfate (Subpart M)
Calcium Chloride (Subpart D)
Sodium Chloride (Subpart P)
Sodium Sulfite (Subpart T)
Aluminum Sulfate (Subpart B)
Potassium Dichromate (Subpart L)

The following subcategories are excluded under Paragraph 8(a)(iv) of the Settlement Agreement because the amount and the toxicity of each pollutant observed in samples collected from plants in each subcategory does not justify developing national regulations:

Ammonium Chloride (Subpart X)
Ammonium Hydroxide (Subpart Y)
Barium Carbonate (Subpart Z)
Calcium Carbonate (Subpart AD)
Carbon Dioxide (Subpart AF)
Carbon Monoxide/Hydrogen (Subpart AG)
Hydrochloric Acid (Subpart G)
Hydrogen Peroxide (Organic Process) (Subpart I)
Nitric Acid (strong) (Subpart AV)
Oxygen and Nitrogen (Subpart AW)
Potassium Iodide (Subpart AV)
Sodium Hydrosulfide (Subpart BD)
Sodium Metal (Subpart R)
Sodium Silicate (Subpart S)
Sodium Thiosulfate (Subpart BG)
Sulfur Dioxide (Subpart BG)
Sulfuric Acid (Subpart U)
Nitric Acid (Subpart J)
Sodium Hydrosulfite (Subpart BE)

The following subcategories are excluded under Paragraph 8(a)(iv) of the Revised Settlement Agreement because these subcategories consist of only one plant or one known discharger.

Zinc Oxide (Subpart BJ)
Lithium Carbonate (Subpart AS)
Manganese Sulfate (Subpart AT)
Sodium Carbonate (Subpart O)
Boric Acid (Subpart AB)
Hydrogen Peroxide (Electrolytic Process) (Subpart I)
Cuprous Oxide (Subpart AK)
Potassium Permanganate (Subpart AZ)
Ferrous Sulfate (Subpart AM)

The following subcategories are excluded from categorical pretreatment regulations for existing sources under paragraph 8(b) of the Revised Settlement Agreement because there are no existing indirect dischargers:

Hydrofluoric Acid (Subpart H)
Sodium Dichromate and Sodium Sulfate (Subpart Q)
Titanium Dioxide (Chloride Process) (Subpart V)
Titanium Dioxide (Chloride/Ilmenite Process) (Subpart V)

The following subcategories are excluded from categorical pretreatment regulations for existing sources under paragraph 8(b) of the Revised Settlement Agreement because the concentrations of toxic pollutants in effluent to POTW from existing sources are below treatable levels.

Chlor-Alkali (Mercury Cells) (Subpart F)
Titanium Dioxide (Sulfate Process) (Subpart V)
Hydrogen Cyanide (Subpart AP)

The following subcategory is excluded from categorical pretreatment regulations for existing sources under paragraph 8(b)(ii) of the Revised Settlement Agreement because the amount and toxicity of incompatible pollutants in effluent to POTW from existing sources is too insignificant to justify developing a pretreatment regulation:

Sodium Bisulfite (Subpart BB)

Appendix E—Subcategories To Be Deferred To Phase II Study

Beryllium Oxide (2819)
Chromium Sulfate (2819)
Chromium Oxide (2819)
Copper Chloride (2819)
Copper Iodide (2819)
Lead Silicate (2819)
Lead Arsenate (2819)
Mercury Chloride (2819)
Mercury Oxide (2819)
Nickel Ammonium Sulfate (2819)
Nickel Carbonate (2819)
Nickel Chloride (2819)
Nickel Fluoroborate (2819)
Nickel Nitrate (2819)
Potassium Cyanide (2819)
Silver Bromide (2819)
Silver Chloride (2819)
Silver Carbonate (2819)
Silver Cyanide (2819)
Silver Iodide (2819)
Silver Oxide (2819)
Sodium Antimonate (2819)
Sodium Cyanide (2819)
Zinc Chloride (2819)
Zinc Sulfide (2819)
White Lead Pigment ($Pb(OH)_2 + PbCO_3$) (2816)
Lead Dioxide, Brown (PbO_2) (2816)
Lead Dioxide, Red (Pb_2O_3) (2816)
Potassium Carbonate (2812)
Gases, Industrial Compressed Liquid or Solid (2813)
Nitrous Oxide (2813)
Barium Sulfate (2816)
Barytes Pigments (2816)
Iron Colors (2816)
Iron Oxide, Black (2816)
Iron Oxide, Magnetic (2816)
Iron Oxide, Yellow (2816)
Others (2816)
Satin White Pigment (2816)
Siennas (2816)
Ultramarine Pigment (2816)
Umbers (2816)
Whiting (2816)
Aluminum Compounds (2819)
Aluminum Hydroxide (2819)
Aluminum Oxide (2819)
Alums (2819)
Ammonia Alum (2819)
Ammonium Molybdate (2819)
Ammonium Compounds (2819)
Ammonium Perchlorate (2819)
Ammonium Thiosulfate (2819)
Barium Compounds (2819)
Bleaching Powder (2819)
Boron Compounds (not produced at mines) (2819)
Borosilicate (2819)
Brine (2819)
Calcium Hypochlorite (2819)
Calcium Compounds (inorg) (2819)
Cerium Salts (2819)
Chlorosulfuric Acid (2819)
Cobalt Chloride (2819)
Cobalt 60 (radioactive) (2819)
Cobalt Sulfate (2819)
Fissionable Materials Production (2819)
Heavy Water (2819)
Hydrated Alumina Silicate Powder (2819)
Hydrogen Sulfide (2819)
Hydrophosphites (2819)
Indium Chloride (2819)

- Inorganic Acids (except HNO₃ or H₃PO₄) (2819)
- Iodides (2819)
- Isotopes Radioactive (2819)
- Lithium Compounds (2819)
- Luminous Compounds (radium) (2819)
- Magnesium Compounds (inorg) (2819)
- Manganese Dioxide (powder synthetic) (2819)
- Nuclear Cores, Inorganic (2819)
- Nuclear Fuel Reactor Cases, Inorganic (2819)
- Nuclear Fuel Scrap Re-Processing (2819)
- Oleum (fuming sulfuric acid) (2819)
- Oxidation Catalyst from Porcelain (2819)
- Perchloric Acid (2819)
- Peroxides, Inorganic (2819)
- Potash Alum (2819)
- Potassium Aluminum Sulfate (2819)
- Potassium Bromide (2819)
- Potassium Chlorate (2819)
- Potassium Compounds Inorganic (except KOH and K₂CO₃) (2819)
- Potassium Hypochlorite (2819)
- Potassium Nitrate and Sulfate (2819)
- Radium Chloride (2819)
- Radium Luminous Compounds (2819)
- Rare Earth Metal Salts (2819)
- Reagent Grade Chemicals (inorganics refined from technical grades) (2819)
- Salts of Rare Earth Metals (2819)
- Silica Amorphous (2819)
- Silica Gel (2819)
- Soda Alum (2819)
- Sodium Chlorate (2819)
- Sodium Compounds, Inorganic (2819)
- Stannic and Stannous Chloride (2819)
- Strontium Carbonate (precipitated and oxide) (2819)
- Strontium Nitrate (2819)
- Potash Magnesia (2819)
- Sulfides and Sulfites (2819)
- Sulfocyanides (2819)
- Sulfur Chloride (2819)
- Sulfur Hexafluoride (2819)
- Sulfur (recovered or refined including sour natural gas) (2819)
- Thiocyanates, Inorganic (2819)
- Tin Compounds, Inorganic (2819)
- Uranium Slag, Radioactive (2819)
- Sodium Hydrosulfite (Zinc Process)
- Silver Nitrate (2819)
- Sodium Silicofluoride (2819)
- Aluminum Chloride (2819)

The following subcategories involve only indirect discharges:

- Bromine (Subpart AC)
- Calcium Oxide (Subpart E)
- Chromic Acid (Subpart AI)
- Calcium Hydroxide (Subpart AE)
- Fluorine (Subpart AN)
- Hydrogen (Subpart AO)
- Iodine (Subpart AQ)
- Potassium Chloride (Subpart AX)
- Stannic Oxide (Subpart BH)
- Zinc Sulfate (Subpart BK)
- Calcium Carbide (Subpart C)
- Potassium Metal (Subpart K)
- Sodium Bicarbonate (Subpart N)
- Borax (Subpart AA)
- Ferric Chloride (Subpart AL)
- Lead Monoxide (Subpart AR)
- Sodium Fluoride (Subpart BC)
- Potassium Sulfate (Subpart M)
- Calcium Chloride (Subpart D)
- Sodium Chloride (Subpart P)

- Sodium Sulfite (Subpart T)
- Aluminum Sulfate (Subpart B)
- Potassium Dichromate (Subpart L)

List of Subjects in 40 CFR Part 415

Inorganic chemicals Water pollution control, Waste treatment and disposal.

EPA has amended 40 CFR Chapter I by revising Part 415 to read as follows:

PART 415—INORGANIC CHEMICALS MANUFACTURING POINT SOURCE CATEGORY

Subpart A—Aluminum Chloride Production Subcategory

Sec.

- 415.10 Applicability; description of the aluminum chloride production subcategory.
- 415.11 Specialized definitions. [Reserved]
- 415.12 [Reserved]
- 415.13 [Reserved]
- 415.14 Pretreatment standards for existing sources (PSES).
- 415.15 [Reserved]

Subpart B—Aluminum Sulfate Production Subcategory

- 415.20 Applicability; description of the aluminum sulfate production subcategory.
- 415.21 Specialized definitions. [Reserved]
- 415.22 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.23 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.24 Pretreatment standards for existing sources (PSES).
- 415.25 New source performance standards (NSPS).
- 415.26 Pretreatment standards for new sources (PSNS).

Subpart C—Calcium Carbide Production Subcategory

- 415.30 Applicability; description of the calcium carbide production subcategory.
- 415.31 Specialized definitions. [Reserved]
- 415.32 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.33 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.34 [Reserved]
- 415.35 New source performance standards (NSPS).
- 415.36 Pretreatment standards for new sources (PSNS).

Subpart D—Calcium Chloride Production Subcategory

- 415.40 Applicability; description of the calcium chloride production subcategory.

- 415.41 Specialized definitions.
- 415.42 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.43 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.44 [Reserved]
- 415.45 New source performance standards (NSPS).
- 415.46 Pretreatment standards for new sources (PSNS).

Subpart E—Calcium Oxide Production Subcategory

- 415.50 Applicability; description of the calcium oxide production subcategory.
- 415.51 Specialized definitions. [Reserved]
- 415.52 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.53 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.54 [Reserved]
- 415.55 New source performance standards (NSPS).
- 415.56 Pretreatment standards for new sources (PSNS).

Subpart F—Chlor-alkali Subcategory (Chlorine and Sodium or Potassium Hydroxide Production)

- 415.60 Applicability; description of the chlorine and sodium or potassium hydroxide production subcategory.
- 415.61 Specialized definitions.
- 415.62 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.63 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.64 Pretreatment standards for existing sources (PSES).
- 415.65 New source performance standards (NSPS).
- 415.66 Pretreatment standards for new sources (PSNS).
- 415.67 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Subpart G—Hydrochloric Acid Production Subcategory [Reserved]

Subpart H—Hydrofluoric Acid Production Subcategory

- 415.80 Applicability; description of the hydrofluoric acid production subcategory.
- 415.81 Specialized definitions. [Reserved]

415.82 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.83 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.84 [Reserved]

415.85 New source performance standards (NSPS).

415.86 Pretreatment standards for new sources (PSNS).

415.87 [Reserved]

Subpart I—Hydrogen Peroxide Production Subcategory

415.90 Applicability; description of the hydrogen peroxide production subcategory.

415.91 Specialized definitions.

415.92 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart J—Nitric Acid Production Subcategory [Reserved]

Subpart K—Potassium Metal Production Subcategory

415.110 Applicability; description of the potassium metal production subcategory.

415.111 Specialized definitions. [Reserved]

415.112 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.113 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.114 [Reserved]

415.115 New source performance standards (NSPS).

415.116 Pretreatment standards for new sources (PSNS).

Subpart L—Potassium Dichromate Production Subcategory

415.120 Applicability; description of the potassium dichromate production subcategory.

415.121 Specialized definitions. [Reserved]

415.122 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.123 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.124 Pretreatment standards for existing sources (PSES).

415.125 New source performance standards (NSPS).

415.126 Pretreatment standards for new sources (PSNS).

Subpart M—Potassium Sulfate Production Subcategory

415.130 Applicability; description of the potassium sulfate production subcategory.

415.131 Specialized definitions. [Reserved]

415.132 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.133 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.134 [Reserved]

415.135 New source performance standards (NSPS).

415.136 Pretreatment standards for new sources (PSNS).

Subpart N—Sodium Bicarbonate Production Subcategory

415.140 Applicability; description of the sodium bicarbonate production subcategory.

415.141 Specialized definitions. [Reserved]

415.142 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.143 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.144 [Reserved]

415.145 New source performance standards (NSPS).

415.146 Pretreatment standards for new sources (PSNS).

Subpart O—Sodium Carbonate Production Subcategory [Reserved]

Subpart P—Sodium Chloride Production Subcategory

415.160 Applicability; description of the sodium chloride production subcategory.

415.161 Specialized definitions.

415.162 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.163 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.164 [Reserved]

415.165 New source performance standards (NSPS).

415.166 Pretreatment standards for new sources (PSNS).

Subpart Q—Sodium Dichromate and Sodium Sulfate Production Subcategory

415.170 Applicability; description of the sodium dichromate and sodium sulfate production subcategory.

415.171 Specialized definitions.

415.172 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of

the best practicable control technology currently available (BPT).

415.173 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.174 [Reserved]

415.175 New source performance standards (NSPS).

415.176 Pretreatment standards for new sources (PSNS).

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

Subpart R—Sodium Metal Production Subcategory [Reserved]

Subpart S—Sodium Silicate Production Subcategory [Reserved]

Subpart T—Sodium Sulfite Production Subcategory

415.200 Applicability; description of the sodium sulfite production subcategory.

415.201 Specialized definitions.

415.202 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.203 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.204 [Reserved]

415.205 New source performance standards (NSPS).

415.206 Pretreatment standards for new sources (PSNS).

Subpart U—Sulfuric Acid Production Subcategory [Reserved]

Subpart V—Titanium Dioxide Production Subcategory

415.220 Applicability; description of the titanium dioxide production subcategory.

415.221 Specialized definitions.

415.222 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.223 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.224 [Reserved]

415.225 New source performance standards (NSPS).

415.226 Pretreatment standards for new sources (PSNS).

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

Subpart W—Aluminum Fluoride Production Subcategory

- 415.230 Applicability; description of the aluminum fluoride production subcategory.
- 415.231 Specialized definitions.
- 415.232 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.233 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.234 [Reserved]
- 415.235 New Source performance standards (NSPS).
- 415.236 [Reserved]
- 415.237 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Subpart X—Ammonium Chloride Production Subcategory

- 415.240 Applicability; description of the ammonium chloride production subcategory.
- 415.241 Specialized definitions.
- 415.242 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart Y—Ammonium Hydroxide Production Subcategory—[Reserved]**Subpart Z—Barium Carbonate Production Subcategory—[Reserved]****Subpart AA—Borax Production Subcategory**

- 415.270 Applicability; description of the borax production subcategory.
- 415.271 Specialized definitions. [Reserved]
- 415.272 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AB—Boric Acid Production Subcategory

- 415.280 Applicability; description of the boric acid production subcategory.
- 415.281 Specialized definitions.
- 415.282 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AC—Bromine Production Subcategory

- 415.290 Applicability; description of the bromine production subcategory.
- 415.291 Specialized definitions. [Reserved]
- 415.292 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AD—Calcium Carbonate Production Subcategory

- 415.300 Applicability; description of the calcium carbonate production subcategory.
- 415.301 Specialized definitions.
- 415.302 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AE—Calcium Hydroxide Production Subcategory

- 415.310 Applicability; description of the calcium hydroxide production subcategory.
- 415.311 Specialized definitions.
- 415.312 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AF—Carbon Dioxide Production Subcategory [Reserved]**Subpart AG—Carbon Monoxide and By-product Hydrogen Production Subcategory**

- 415.330 Applicability; description of the carbon monoxide and by-product hydrogen production subcategory.
- 415.331 Specialized definitions.
- 415.332 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AH—Chrome Pigments Production Subcategory

- 415.340 Applicability; description of the chrome pigments production subcategory.
- 415.341 Specialized definitions.
- 415.342 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.343 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.344 Pretreatment standards for existing sources (PSES).
- 415.345 New source performance standards (NSPS).
- 415.346 Pretreatment standards for new sources (PSNS).
- 415.347 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Subpart AI—Chromic Acid Production Subcategory

- 415.350 Applicability; description of the chromic acid production subcategory.
- 415.351 Specialized definitions. [Reserved]
- 415.352 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AJ—Copper Sulfate Production Subcategory

- 415.360 Applicability; description of the copper sulfate production subcategory.
- 415.361 Specialized definitions.
- 415.362 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.363 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
- 415.364 Pretreatment standards for existing sources (PSES).
- 415.365 New source performance standards (NSPS).
- 415.366 Pretreatment standards for new sources (PSNS).
- 415.367 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

Subpart AK—Cuprous Oxide Production Subcategory—[Reserved]**Subpart AL—Ferric Chloride Production Subcategory**

- 415.380 Applicability; description of the ferric chloride production subcategory.
- 415.381 Specialized definitions.
- 415.382 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
- 415.383 [Reserved]
- 415.384 Pretreatment standards for existing sources (PSES).

Subpart AM—Ferrous Sulfate Production Subcategory—[Reserved]**Subpart AN—Fluorine Production Subcategory**

- 415.400 Applicability; description of the fluorine production subcategory.
- 415.401 Specialized definitions.
- 415.402 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AO—Hydrogen Production Subcategory

- 415.410 Applicability; description of the hydrogen production subcategory.
- 415.411 Specialized definitions.
- 415.412 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AP—Hydrogen Cyanide Production Subcategory

- 415.420 Applicability; description of the hydrogen cyanide production subcategory.
- 415.421 Specialized definitions.

415.422 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.423 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.424 [Reserved]

415.425 New source performance standards (NSPS).

415.426 Pretreatment standards for new sources (PSNS).

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

Subpart AQ—Iodine Production Subcategory

415.430 Applicability; description of the iodine production subcategory.

415.431 Specialized definitions.

415.432 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AR—Lead Monoxide Production Subcategory

415.440 Applicability; description of the lead monoxide production subcategory.

415.441 Specialized definitions.

415.442 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.443 [Reserved]

415.444 Pretreatment standards for existing sources (PSES).

Subpart AS—Lithium Carbonate Production Subcategory

415.450 Applicability; description of the lithium carbonate production subcategory.

415.451 Specialized definitions.

415.452 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AT—Manganese Sulfate Production Subcategory—[Reserved]

Subpart AU—Nickel Sulfate Production Subcategory

415.470 Applicability; description of the nickel sulfate production subcategory.

415.471 Specialized definitions.

415.472 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.473 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

415.474 Pretreatment standards for existing sources (PSES).

415.475 New source performance standards (NSPS).

415.476 Pretreatment standards for new sources (PSNS).

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

Subpart AV—Strong Nitric Acid Production Subcategory—[Reserved]

Subpart AW—Oxygen and Nitrogen Production Subcategory

415.490 Applicability; description of the oxygen and nitrogen production subcategory.

415.491 Specialized definitions. [Reserved]

415.492 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AX—Potassium Chloride Production Subcategory

415.500 Applicability; description of the potassium chloride production subcategory.

415.501 Specialized definitions. [Reserved]

415.502 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AY—Potassium Iodide Production Subcategory

415.510 Applicability; description of the potassium iodide production subcategory.

415.511 Specialized definitions.

415.512 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart AZ—Potassium Permanganate Production Subcategory—[Reserved]

Subpart BA—Silver Nitrate Production Subcategory

415.530 Applicability; description of the silver nitrate production subcategory.

415.531 Specialized definitions.

415.532 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.533 [Reserved]

415.534 Pretreatment standards for existing sources (PSES).

Subpart BB—Sodium Bisulfite Production Subcategory

415.540 Applicability; description of the sodium bisulfite production subcategory.

415.541 Specialized definitions.

415.542 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.543 Effluent limitations guidelines representing the degree of effluent

reduction attainable by the application of the best available technology economically achievable (BAT).

415.544 [Reserved]

415.545 New source performance standards (NSPS).

415.546 Pretreatment standards for new sources (PSNS).

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

Subpart BC—Sodium Fluoride Production Subcategory

415.550 Applicability; description of the sodium fluoride production subcategory.

415.551 Specialized definitions.

415.552 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

415.553 [Reserved]

415.554 Pretreatment standards for existing sources (PSES).

Subpart BD—Sodium Hydrosulfide Production Subcategory—[Reserved]

Subpart BE—Sodium Hydrosulfide Production Subcategory—[Reserved]

Subpart BF—Sodium Silicofluoride Production Subcategory—[Reserved]

Subpart BG—Sodium Thiosulfate Production Subcategory—[Reserved]

Subpart BH—Stannic Oxide Production Subcategory

415.600 Applicability; description of the stannic oxide production subcategory.

415.601 Specialized definitions.

415.602 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Subpart BI—Sulfur Dioxide Production Subcategory—[Reserved]

Subpart BJ—Zinc Oxide Production Subcategory—[Reserved]

Subpart BK—Zinc Sulfate Production Subcategory

415.630 Applicability; description of the zinc sulfate production subcategory.

415.631 Specialized definitions.

415.632 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Authority: Sections 301, 304 (b), (c), (e), and (g), 306 (b) and (c), 307 (b) and (c), and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, as amended by the Clean Water Act of 1977) (the "Act"); 33 U.S.C. 1311, 1314 (b), (c), (e), and (g), 1316 (b) and (c), 1317 (b) and (c), and 1361; 86 Stat. 816, Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

Subpart A—Aluminum Chloride Production Subcategory

§ 415.10 Applicability; description of the aluminum chloride production subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into treatment works which are publicly owned resulting from the production of aluminum chloride.

§ 415.11 Specialized definitions. [Reserved]

§ 415.12 [Reserved]

§ 415.13 [Reserved]

§ 415.14 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART A—ALUMINUM CHLORIDE

Pollutant or pollutant property	PSES limitations
pH.....	Within the range 5.0 to 10.0.

§ 415.15 [Reserved]

Subpart B—Aluminum Sulfate Production Subcategory

§ 415.20 Applicability; description of the aluminum sulfate production subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into treatment works which are publicly owned resulting from the production of aluminum sulfate.

§ 415.21 Specialized definitions. [Reserved]

§ 415.22 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

(a) Subject to the provisions of paragraphs (b), (c) and (d) of this section, there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed and operated so as to contain the precipitation from the 10-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 10-year, 24-hour rainfall event, when such event occurs.

(c) During any calendar month there may be discharged from a process wastewater impoundment either a volume of process wastewater equal to the difference between the precipitation for that month that falls within the impoundment and the evaporation for that month, or if greater, a volume of process wastewater equal to the difference between the mean precipitation for that month that falls within the impoundment and the mean evaporation for that month as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located (or as otherwise determined if no monthly data have been established by the National Climatic Center).

(d) Any process wastewater discharged pursuant to paragraph (c) of this section shall comply with each of the following requirements:

SUBPART B—ALUMINUM SULFATE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
TSS.....	50	25
pH.....	(¹)	(¹)

¹ Within the range 5.0 to 9.0.

§ 415.23 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

(a) Subject to the provisions of paragraph (b) of this section there shall

be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed, and operated so as to contain the precipitation from the 25-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 25-year, 24-hour rainfall event, when such event occurs.

§ 415.24 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART B—ALUMINUM SULFATE

Pollutant or pollutant property	PSES limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Zinc.....	5.0	2.5

§ 415.25 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

(a) Subject to the provisions of paragraph (b) of this section there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed, and operated so as to contain the precipitation from the 25-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 25-year, 24-hour rainfall event, when such event occurs.

§ 415.26 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as the new source performance standards specified in § 415.25.

Subpart C—Calcium Carbide Production Subcategory**§ 415.30 Applicability; description of the calcium carbide production subcategory.**

The provisions of this subpart are applicable to discharges resulting from the production of calcium carbide in uncovered furnaces.

§ 415.31 Specialized definitions. [Reserved]**§ 415.32 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).**

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.33 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.34 [Reserved]**§ 415.35 New source performance standards (NSPS).**

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.36 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart D—Calcium Chloride Production Subcategory**§ 415.40 Applicability; description of the calcium chloride production subcategory.**

The provisions of this subpart are applicable to discharges resulting from the production of calcium chloride by the brine extraction process.

§ 415.41 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean calcium chloride.

§ 415.42 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART D—CALCIUM CHLORIDE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
TSS.....	0.016	0.0082
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.43 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available

technology economically achievable (BAT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.44 [Reserved]**§ 415.45 New source performance standards (NSPS).**

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.46 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart E—Calcium Oxide Production Subcategory**§ 415.50 Applicability; description of the calcium oxide production subcategory.**

The provisions of this subpart are applicable to discharges resulting from the production of calcium oxide.

§ 415.51 Specialized definitions. [Reserved]**§ 415.52 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).**

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

(a) Subject to the provisions of paragraphs (b), (c), and (d) of this section, there shall be no discharge of process wastewater pollutants to navigable waters.

(b) A process wastewater impoundment which is designed, constructed and operated so as to contain the precipitation from the 10-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the

volume of precipitation that falls within the impoundment in excess of that attributable to the 10-year, 24-hour rainfall event, when such event occurs.

(c) During any calendar month there may be discharged from a process wastewater impoundment either a volume of process wastewater equal to the difference between the precipitation for that month that falls within the impoundment and the evaporation for that month, or, if greater, a volume of process wastewater equal to the difference between the mean precipitation for that month that falls within the impoundment and the mean evaporation for that month as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located (or as otherwise determined if no monthly data have been established by the National Climatic Center).

(d) Any process wastewater discharged pursuant to paragraph (c) of this section shall comply with each of the following requirements:

SUBPART E—CALCIUM OXIDE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
TSS.....	50	25
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.53 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

(a) Subject to the provisions of paragraph (b) of this section there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed, and operated so as to contain the precipitation from the 25-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process

wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 25-year, 24-hour rainfall event, when such event occurs.

§ 415.54 [Reserved]

§ 415.55 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

(a) Subject to the provisions of paragraph (b) of this section there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed, and operated so as to contain the precipitation from the 25-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 25-year, 24-hour rainfall event, when such event occurs.

§ 415.56 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as the new source performance standards specified in § 415.55.

Subpart F—Chlor-alkali Subcategory (Chlorine and Sodium or Potassium Hydroxide Production)

§ 415.60 Applicability; description of the chlorine and sodium or potassium hydroxide production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of chlorine and sodium or potassium hydroxide by the diaphragm cell process and by the mercury cell process.

§ 415.61 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean chlorine.

(c) The term "mercury" shall mean the total mercury present in the process wastewater stream exiting the mercury treatment system.

(d) The term "lead" shall mean total lead.

§ 415.62 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart and using the mercury cell process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART F—CHLOR-ALKALI MERCURY CELLS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	0.64	0.32
Mercury (T).....	.00028	.00014
pH.....	(¹)	(¹)

¹ Within the range of 6.0 to 9.0.

(b) Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart and using the diaphragm cell process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART F—CHLOR-ALKALI DIAPHRAGM CELLS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	1.1	0.51
Copper (T).....	0.018	0.0070
Lead (T).....	0.026	0.010
Nickel (T).....	0.014	0.0056
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.63 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart and using the

mercury cell process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

SUBPART F—CHLOR-ALKALI-MERCURY CELLS

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
Mercury (T).....	0.00023	0.00010
Total Residual Chlorine.....	0.0032	0.0019

(b) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the diaphragm cell process must achieve the following effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

SUBPART F—CHLOR-ALKALI-DIAPHRAGM CELLS

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
Copper (T).....	0.012	0.0049
Lead (T).....	0.0059	0.0024
Nickel (T).....	0.0097	0.0037
Total Residual Chlorine.....	0.013	0.0079

§ 415.64 Pretreatment standards for existing sources (PSES).

(a) [Reserved]

(b) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart and using the diaphragm cell process, which introduces pollutants into a publicly owned treatment works, must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART F—CHLOR-ALKALI-DIAPHRAGM CELLS

Pollutant or pollutant property	PSES effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Copper (T).....	2.1	0.80
Lead (T).....	2.9	1.1
Nickel (T).....	1.6	0.64

In cases when POTWs find it necessary to impose mass limitations, the

following equivalent mass limitations are provided as an alternate: The limitations for Copper (T), Lead (T) and Nickel (T) are the same as specified in § 415.62(b).

§ 415.65 New source performance standards (NSPS).

(a) Any new source subject to this subpart and using the mercury cell process must achieve the following new source performance standards (NSPS):

SUBPART F—CHLOR-ALKALI-MERCURY CELLS

Pollutant or pollutant property	NSPS limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	0.64	0.32
Mercury (T).....	0.00023	0.00010
Total Residual Chlorine.....	0.0032	0.0019
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

(b) Any new source subject to this subpart and using the diaphragm cell process must achieve the following new source performance standards (NSPS):

SUBPART F—CHLOR-ALKALI-DIAPHRAGM CELLS

Pollutant or pollutant property	NSPS limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	1.1	0.51
Lead (T).....	0.0047	0.0019
Total Residual Chlorine.....	0.013	0.0079
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.66 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart and using the mercury cell process, which introduces pollutants into a publicly owned treatment works, must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as specified in § 415.64(a).

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart and using the diaphragm cell process, which introduces pollutants into a publicly owned treatment works, must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS):

SUBPART F—DIAPHRAGM CELLS

Pollutant or pollutant property	PSNS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Lead (T).....	0.53	0.21

In cases where POTWs find it necessary to impose mass limitations, the following equivalent mass limitations are provided as an alternate: The limitations for Lead (T) are the same as specified in § 415.65(b).

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

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the mercury cell process must 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 are the same for TSS and pH as specified in § 415.62(a).

(b) [Reserved]

Subpart G—Hydrochloric Acid Production Subcategory [Reserved]

Subpart H—Hydrofluoric Acid Production Subcategory

§ 415.80 Applicability; description of the hydrofluoric acid production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of hydrofluoric acid.

§ 415.81 Specialized definitions. [Reserved]

§ 415.82 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART H—HYDROFLUORIC ACID

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	11.0	5.3
Fluoride (T).....	6.1	2.9
Nickel (T).....	0.036	0.011
Zinc (T).....	0.12	0.036
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.83 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

SUBPART H—HYDROFLUORIC ACID

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
Fluoride (T).....	3.4	1.6
Nickel (T).....	0.020	0.0060
Zinc (T).....	0.072	0.022

§ 415.84 [Reserved]

§ 415.85 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

SUBPART H—HYDROFLUORIC ACID

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	6.0	3.0
Fluoride (T).....	3.4	1.6
Nickel (T).....	0.020	0.0060
Zinc (T).....	0.072	0.022
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.86 Pretreatment standards for new sources (PSNS).

Except as provided for in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as specified in § 415.84.

§ 415.87 [Reserved]

Subpart I—Hydrogen Peroxide Production Subcategory

§ 415.90 Applicability; description of the hydrogen peroxide production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of hydrogen peroxide by the electrolytic process and by the oxidation of alkyl hydroanthraquinones.

§ 415.91 Specialized definitions.

For the purpose of this subpart: (a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean hydrogen peroxide as a one hundred percent hydrogen peroxide solution.

(c) The term "Cyanide A" shall mean those cyanides amenable to chlorination and is determined by the methods specified in 40 CFR 136.3.

(d) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated non-process wastewater, as defined below.

(e) The term "process wastewater pollutants" means pollutants present in process wastewater.

(f) The term "contaminated nonprocess wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal

safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.92 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart and manufacturing hydrogen peroxide by the oxidation of alkyl hydroanthraquinones must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART I—HYDROGEN PEROXIDE ORGANIC PROCESS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	0.80	0.40
TOC.....	0.44	0.22
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

(b) Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart and manufacturing hydrogen peroxide by the electrolytic process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART I—HYDROGEN PEROXIDE ELECTROLYTE PROCESS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	0.0050	0.0025
Cyanide A.....	0.00040	0.00020
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

Subpart J—Nitric Acid Production Subcategory [Reserved]

Subpart K—Potassium Metal Production Subcategory

§ 415.110 Applicability; description of the potassium metal production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of potassium metal.

§ 415.111 Specialized definitions. [Reserved]

§ 415.112 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.113 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.114 [Reserved]

§ 415.115 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.116 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment

standards for new sources (PSNS): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart L—Potassium Dichromate Production Subcategory

§ 415.120 Applicability; description of the potassium dichromate production subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants resulting from the production of potassium dichromate into treatment works which are publicly owned.

§ 415.121 Specialized definitions. [Reserved]

§ 415.122 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.123 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.124 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART L—POTASSIUM DICHROMATE

Pollutant or pollutant property	PSES limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Hexavalent chromium.....	0.25	0.090
Total chromium.....	3.0	1.0

§ 415.125 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.126 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart M—Potassium Sulfate Production Subcategory

§ 415.130 Applicability; description of the potassium sulfate production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of potassium sulfate.

§ 415.131 Specialized definitions. [Reserved]

§ 415.132 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

(a) Subject to the provisions of paragraphs (b), (c), and (d) of this section, there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed and operated so as to contain the precipitation from the 10-year, 24-hour rainfall event as established by the National Climatic

Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 10-year, 24-hour rainfall event, when such event occurs.

(c) During any calendar month there may be discharged from a process wastewater impoundment either a volume of process wastewater equal to the difference between the precipitation for that month that falls within the impoundment and the evaporation for that month, or, if greater, a volume of process wastewater equal to the difference between the mean precipitation for that month that falls within the impoundment and the mean evaporation for that month as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located (or as otherwise determined if no monthly data have been established by the National Climatic Center).

(d) Any process wastewater discharged pursuant to paragraph (c) of this section shall comply with each of the following requirements:

SUBPART M—POTASSIUM SULFATE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
TSS.....	50	25
ph.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.133 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

(a) Subject to the provisions of paragraph (b) of this section there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed, and operated so as to contain the precipitation from the 25-year, 24-hour rainfall event as

established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 25-year, 24-hour rainfall event, when such event occurs.

§ 415.134 [Reserved]

§ 415.135 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

(a) Subject to the provisions of paragraph (b) of this section there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed, and operated so as to contain the precipitation from the 25-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 25-year, 24-hour rainfall event, when such event occurs.

§ 415.136 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as the new source performance standards specified in § 415.135.

Subpart N—Sodium Bicarbonate Production Subcategory

§ 415.140 Applicability; description of the sodium bicarbonate production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of sodium bicarbonate.

§ 415.141 Specialized definitions. [Reserved]

§ 415.142 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject

to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.143 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.144 [Reserved]

§ 415.145 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.146 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart O—Sodium Carbonate Production Subcategory [Reserved]

Subpart P—Sodium Chloride Production Subcategory

§ 415.160 Applicability; description of the sodium chloride production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of sodium chloride by the solution brine-mining process and by the solar evaporation process.

§ 415.161 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and

methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean sodium chloride.

(c) The term "bitterns" shall mean the saturated brine solution remaining after precipitation of sodium chloride in the solar evaporation process.

§ 415.162 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the solar evaporation process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except that unused bitterns may be returned to the body of water from which the process brine solution was originally withdrawn, provided no additional pollutants are added to the bitterns during the production of sodium chloride.

(b) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the solution brine mining process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART P—SODIUM CHLORIDE BRINE MINING PROCESS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb.) of product	
TSS.....	0.34	0.17
pH.....	(¹)	(¹)

¹ Within the range of 6.0 to 9.0.

§ 415.163 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the solar evaporation process must achieve

the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): There shall be no discharge of process wastewater pollutants to navigable waters, except that unused bitterns may be returned to the body of water from which the process brine solution was originally withdrawn, provided no additional pollutants are added to the bitterns during the production of sodium chloride.

(b) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the solution brine mining process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.164 [Reserved]

§ 415.165 New source performance standards (NSPS).

(a) Any new source subject to this subpart and using the solar evaporation process must achieve the following new source performance standards (NSPS): There shall be no discharge of process wastewater pollutants to navigable waters, except that unused bitterns may be returned to the body of water from which the process brine solution was originally withdrawn, provided no additional pollutants are added to the bitterns during the production of sodium chloride.

(b) Any new source subject to this subpart and using the solution brine mining process must achieve the following new source performance standards (NSPS): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.166 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as the new source performance standards specified in § 415.165.

Subpart Q—Sodium Dichromate and Sodium Sulfate Production Subcategory

§ 415.170 Applicability; description of the sodium dichromate and sodium sulfate production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of sodium dichromate and by-product sodium sulfate.

§ 415.171 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean sodium dichromate.

(c) The term "Cr(T)" shall mean total chromium.

(d) The term "Cr(+6)" shall mean hexavalent chromium.

§ 415.172 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART Q—SODIUM DICHROMATE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb.) of product	
TSS.....	0.44	0.22
Hexavalent Chromium.....	0.00090	0.00050
Chromium (T).....	0.0088	0.0044
Nickel (T).....	0.0068	0.0034
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.173 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations for Chromium (T),

Hexavalent Chromium, and Nickel (T) are the same as specified in § 415.172.

§ 415.174 [Reserved]

§ 415.175 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): The limitations are the same as specified in § 415.172.

§ 415.176 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as specified in § 415.174.

§ 415.177 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 40 CFR 125.30-125.32, any existing point source subject to this subpart must 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 are the same for TSS and pH as specified in § 415.172.

Subpart R—Sodium Metal Production Subcategory [Reserved]

Subpart S—Sodium Silicate Production Subcategory [Reserved]

Subpart T—Sodium Sulfite Production Subcategory

§ 415.200 Applicability; description of the sodium sulfite production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of sodium sulfite by reacting sulfur dioxide with sodium carbonate.

§ 415.201 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean sodium sulfite.

§ 415.202 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART T—SODIUM SULFITE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
TSS.....	0.032	0.016
COD.....	3.4	1.7
pH.....	(*)	(*)

* Within the range 6.0 to 9.0.

§ 415.203 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

(a) Subject to the provisions of paragraph (b) of this section there shall be no discharge of process wastewater pollutants into navigable waters.

(b) A process wastewater impoundment which is designed, constructed, and operated so as to contain the precipitation from the 25-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the area in which such impoundment is located may discharge that volume of process wastewater which is equivalent to the volume of precipitation that falls within the impoundment in excess of that attributable to the 25-year, 24-hour rainfall event, when such event occurs.

§ 415.204 [Reserved]

§ 415.205 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): There shall be no discharge of process

wastewater pollutant to navigable waters.

§ 415.206 Pretreatment standards for new sources (PSNS).

Except as provided in § 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as the new source performance standards specified in § 415.205.

Subpart U—Sulfuric Acid Production Subcategory [Reserved]

Subpart V—Titanium Dioxide Production Subcategory

§ 415.220 Applicability; description of the titanium dioxide production subcategory.

This subpart applies to discharges to waters of the United States and introduction of pollutants into publicly owned treatment works resulting from the production of titanium dioxide by the sulfate process, the chloride process, and the simultaneous beneficiation-chlorination (chloride-ilmenite) process.

§ 415.221 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean titanium dioxide.

§ 415.222 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and producing titanium dioxide by the sulfate process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART V—TITANIUM DIOXIDE-SULFATE PROCESS

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
TSS.....	140	38
Chromium (T).....	0.48	0.21

SUBPART V—TITANIUM DIOXIDE-SULFATE
PROCESS—Continued

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Nickel (T).....	0.029	0.014
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

(b) Except as provided for in 40 CFR 125.30-125.32, any existing point source subject to this subpart and producing titanium dioxide by the chloride process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART V—TITANIUM DIOXIDE-CHLORIDE
PROCESS

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	23	6.4
Chromium (T).....	0.057	0.030
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

(c) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and producing titanium dioxide by the simultaneous beneficiation-chlorination (chloride/ilmenite) process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART V—TITANIUM DIOXIDE-CHLORIDE-
ILMENITE PROCESS

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	35	9.6
Chromium (T).....	0.12	0.053
Nickel (T).....	0.072	0.035
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.223 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and producing titanium dioxide by the sulfate process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations are the same for Chromium(T) and Nickel(T) as specified in § 415.222(a).

(b) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and producing titanium dioxide by the chloride process must achieve the following effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations for Chromium(T) are the same as specified in § 415.222(b).

(c) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and producing titanium dioxide by the simultaneous beneficiation-chlorination (chloride-ilmenite) process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations for Chromium(T) and Nickel(T) are the same as specified in § 415.222(c).

§ 415.224 [Reserved]

§ 415.225 New source performance standards (NSPS).

(a) Any new source subject to this subpart producing titanium dioxide by the sulfate process must achieve the following new source performance standards (NSPS):

SUBPART V—TITANIUM DIOXIDE-SULFATE
PROCESS

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	110	30
Iron (T).....	4.1	1.2
Chromium (T).....	0.27	0.14
Nickel (T).....	0.18	0.085
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

(b) Any new source subject to this subpart producing titanium dioxide by the chloride process must achieve the following new source performance standards (NSPS):

SUBPART V—TITANIUM DIOXIDE-CHLORIDE
PROCESS

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	14	4.0
Iron (T).....	0.52	0.16
Chromium (T).....	0.023	0.012
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

(c) Any new source subject to this subpart producing titanium dioxide by the simultaneous beneficiation-chlorination (chloride-ilmenite) process must achieve the following new source performance standards (NSPS):

SUBPART V—TITANIUM DIOXIDE-CHLORIDE-
ILMENITE PROCESS

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	8.4	2.4
Iron (T).....	0.32	0.096
Chromium (T).....	0.014	0.0072
Nickel (T).....	0.020	0.010
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.226 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart and producing titanium dioxide by the sulfate process which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS):

SUBPART V—TITANIUM DIOXIDE—SULFATE
PROCESS

Pollutant or pollutant property	PSNS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Iron (T).....	8.5	2.5
Chromium (T).....	0.57	0.30

SUBPART V—TITANIUM DIOXIDE—SULFATE
PROCESS—Continued

Pollutant or pollutant property	PSNS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Nickel (T).....	0.38	0.20

In cases where POTWs find it necessary to impose mass limitations, the following equivalent mass limitations are provided as an alternate: The limitations for Iron(T), Chromium(T), and Nickel(T) are the same as specified in § 415.225(a).

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart and producing titanium dioxide by the chloride process which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS):

SUBPART V—TITANIUM DIOXIDE-CHLORIDE
PROCESS

Pollutant or pollutant property	PSNS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Iron (T).....	5.3	1.6
Chromium (T).....	0.23	0.12

In cases where POTWs find it necessary to impose mass limitations, the following equivalent mass limitations are provided as guidance: The limitations for Iron(T) and Chromium(T) are the same as specified in § 415.255(b).

(c) Except as provided in § 403.7, any new source subject to this subpart and producing titanium dioxide by the simultaneous beneficiation-chlorination (chloride-ilmenite) process which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS):

SUBPART V—TITANIUM DIOXIDE-CHLORIDE-
ILMENITE PROCESS

Pollutant or pollutant property	PSNS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Iron (T).....	5.3	1.6
Chromium (T).....	0.23	0.12

SUBPART V—TITANIUM DIOXIDE-CHLORIDE-
ILMENITE PROCESS—Continued

Pollutant or pollutant property	PSNS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Nickel (T).....	0.33	0.17

In cases where POTWs find it necessary to impose mass limitations, the following equivalent mass limitations are provided as an alternate: The limitations for Iron (T), Chromium (T), and Nickel (T) are the same as specified in § 415.225(c).

§ 415.227 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 40 CFR 125.30–125.32, any existing point source subject to this subpart must 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 are the same for TSS and pH as specified in § 415.172.

Subpart W—Aluminum Fluoride
Production Subcategory

§ 415.230 Applicability; description of the aluminum fluoride production subcategory.

This subpart applies to discharges to waters of the United States and introduction of pollutants into publicly owned treatment works resulting from the production of aluminum fluoride.

§ 415.231 Specialized definitions:

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" means aluminum fluoride produced by the dry process in which partially dehydrated alumina hydrate is reacted with hydrofluoric acid gas.

§ 415.232 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control

technology currently available (BPT):

SUBPART W—ALUMINUM FLUORIDE

BPT effluent limitations	Pollutant or pollutant property	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	2.4	1.2
Fluoride (T).....	1.3	0.63
Chromium (T).....	0.015	0.0045
Nickel (T).....	0.0079	0.0024
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.233 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations for Fluoride(T), Chromium(T), and Nickel(T) are the same as specified in § 415.232.

§ 415.234 [Reserved]

§ 415.235 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): The limitations are the same as specified in § 415.232.

§ 415.236 [Reserved]

§ 415.237 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 40 CFR 125.30–.32, any existing point source subject to this subpart must 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 are the same for TSS and pH as specified in § 415.232.

Subpart X—Ammonium Chloride
Production Subcategory

§ 415.240 Applicability; description of the ammonium chloride production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of ammonium chloride by

the reaction of anhydrous ammonia with hydrogen chloride gas and by the recovery process from Solvay process wastes.

§ 415.241 Specialized definitions.

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean ammonium chloride.

(c) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated nonprocess wastewater, as defined below.

(d) The term "process wastewater pollutants" means pollutants present in process wastewater.

(e) The term "contaminated nonprocess wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment. Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.242 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart and reacting anhydrous ammonia with hydrogen chloride gas must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

(b) Except as provided in 40 CFR 125.30-.32, any existing point source subject to this subpart and using the recovery process from Solvay process wastes must achieve the following effluent limitations representing the

degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART X—AMMONIUM CHLORIDE SOLVAY PROCESS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
Ammonia (as N).....	8.8	4.4
pH.....	(1)	(1)

¹ Within the range 6.0 to 9.0.

Subpart Y—Ammonium Hydroxide Production Subcategory [Reserved]

Subpart Z—Barium Carbonate Production Subcategory [Reserved]

Subpart AA—Borax Production Subcategory

§ 415.270 Applicability; description of the borax production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of borax by the ore-mining process and by the Trona process.

§ 415.271 Specialized definitions. [Reserved]

§ 415.272 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except that residual brine and depleted liquor may be returned to the body of water from which the process brine solution was originally withdrawn.

Subpart AB—Boric Acid Production Subcategory

§ 415.280 Applicability; description of the boric acid production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of boric acid from ore-mined borax and from borax produced by the Trona process.

§ 415.281 Specialized definitions.

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean boric acid.

§ 415.282 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using borax produced by the Trona process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except that residual brine and depleted liquor may be returned to the body of water from which the process brine solution was originally withdrawn.

(b) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using mined borax must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AB—BORIC ACID MINED BORAX PROCESS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
Arsenic.....	0.0028	0.0014
TSS.....	0.14	0.07
pH.....	(1)	(1)

¹ Within the range 6.0 to 9.0.

Subpart AC—Bromine Production Subcategory

§ 415.290 Applicability; description of the bromine production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of bromine by the brine-mining process and by the Trona process.

§ 415.291 Specialized definitions. [Reserved]

§ 415.292 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except that residual brine and depleted liquor may be returned to the body of water from which the process brine solution was originally withdrawn.

Subpart AD—Calcium Carbonate Production Subcategory

§ 415.300 Applicability; description of the calcium carbonate production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of calcium carbonate by the milk of lime process and by the recovery process from Solvay process wastes.

§ 415.301 Specialized definitions.

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean calcium carbonate.

§ 415.302 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the milk of lime process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AD—CALCIUM CARBONATE MILK OF LIME PROCESS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	0.56	0.28
pH.....	(¹)	(¹)

¹Within the range 6.0 to 9.0.

(b) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the recovery process from Solvay process wastes, must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AD—CALCIUM CARBONATE SOLVAY RECOVERY PROCESS

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	1.16	0.58
pH.....	(¹)	(¹)

¹Within the range 6.0 to 9.0.

Subpart AE—Calcium Hydroxide Production Subcategory

§ 415.310 Applicability; description of the calcium hydroxide production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of calcium hydroxide by the lime slaking process.

§ 415.311 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated nonprocess wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated nonprocess wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: *Provided*, that all

reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.312 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart AF—Carbon Dioxide Production Subcategory [Reserved]

Subpart AG—Carbon Monoxide and By-Product Hydrogen Production Subcategory

§ 415.330 Applicability; description of the carbon monoxide and by-product hydrogen production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of carbon monoxide and by-product hydrogen by the reforming process.

§ 415.331 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "product" shall mean carbon monoxide plus hydrogen.

(c) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated nonprocess wastewater, as defined below.

(d) The term "process wastewater pollutants" means pollutants present in process wastewater.

(e) The term "contaminated nonprocess wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are

repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.332 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AG—CARBON MONOXIDE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
COD.....	0.50	0.25
TSS.....	0.12	0.060
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

Subpart AH—Chrome Pigments Production Subcategory

§ 415.340 Applicability; description of the chrome pigments production subcategory.

This subpart applies to discharges to waters of the United States and introduction of pollutants into publicly owned treatment works resulting from the production of chrome pigments.

§ 415.341 Specialized definitions.

For the purposes of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "chrome pigments" means chrome yellow, chrome orange, molybdate chrome orange, anhydrous and hydrous chromium oxide, chrome green, and zinc yellow.

(c) The term "product" means chrome pigments.

§ 415.342 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AH—CHROME PIGMENTS

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
TSS.....	9.1	3.8
Chromium (T).....	0.31	0.13
Lead (T).....	0.36	0.15
Zinc (T).....	0.31	0.13
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.343 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations for Chromium(T), Lead(T), and Zinc(T) are the same as specified in § 415.342.

§ 415.344 Pretreatment standards for existing sources (PSES).

(a) Existing sources which annually introduce less than 210,000 cubic meters per year (55 million gallons per year) of chrome pigments process wastewater into a publicly owned treatment works are subject only to the standards specified in 40 CFR Part 403.

(b) Except as provided in 40 CFR 403.7 and 403.13 and paragraph (a) of this section, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART AH—CHROME PIGMENTS

Pollutant or pollutant property	PSES effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Chromium (T).....	2.9	1.2
Lead (T).....	3.4	1.4
Zinc (T).....	2.9	1.2

In cases where POTWs find it necessary to impose mass limitations, the following equivalent mass limitations are provided as an alternate: The limitations for Chromium(T), Lead(T), and Zinc(T) are the same as specified in § 415.342.

415.345 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): The limitations are the same as specified in § 415.342.

§ 415.346 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same for TSS and pH as specified in § 415.344.

§ 415.347 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 40 CFR 125.30-125.32, any existing point source subject to this subpart must 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 are the same as specified in § 415.342.

Subpart AI—Chromic Acid Production Subcategory

§ 415.350 Applicability; description of the chromic acid production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of chromic acid in facilities which also manufacture sodium dichromate.

§ 415.351 Specialized definitions.
[Reserved]

§ 415.352 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except as provided for in § 415.172.

Subpart AJ—Copper Sulfate Production Subcategory

§ 415.360 Applicability; description of the copper sulfate production subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into treatment works which are publicly owned resulting from the production of copper sulfate.

§ 415.361 Specialized definitions.

For the purpose of this subpart:
(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean copper sulfate.

§ 415.362 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AJ—COPPER SULFATE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
TSS	0.069	0.023
Copper (T)	0.0030	0.0010
Nickel (T)	0.0060	0.0020
Selenium (T)	0.0015	0.00050
pH	(¹)	(¹)

¹ Within the range of 6.0 to 9.0.

§ 415.363 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations for Copper(T), Nickel(T), and Selenium(T) are the same as specified in § 415.362.

§ 415.364 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART AJ—COPPER SULFATE

Pollutant or pollutant property	PSES effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Copper (T)	3.2	1.1
Nickel (T)	6.4	2.1
Selenium (T)	1.6	0.53

In cases where POTWs find it necessary to impose mass limitations, the following equivalent mass limitations are provided as an alternate: The limitations for Copper (T), Nickel (T), and Selenium (T) are the same as specified in § 415.362.

§ 415.365 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): The limitations are the same as specified in § 415.362.

§ 415.366 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as specified in § 415.364.

§ 415.367 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 40 CFR 125.30-125.32, any existing point source subject to this subpart must 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 are the same for TSS and pH as specified in § 415.362.

Subpart AK—Cuprous Oxide Production Subcategory [Reserved]

Subpart AL—Ferric Chloride Production Subcategory

§ 415.380 Applicability; description of the ferric chloride production subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into treatment works which are publicly owned resulting from the production of ferric chloride from pickle liquor.

§ 415.381 Specialized definitions.

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated nonprocess wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated nonprocess wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.382 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.383 [Reserved]

§ 415.384 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART AL—FERRIC CHLORIDE

Pollutant or pollutant property	PSES limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Total Chromium.....	3.0	1.0
Hexavalent Chromium.....	0.25	0.09
Copper (T).....	1.0	0.50
Nickel (T).....	2.0	1.0
Zinc (T).....	5.0	2.5

Subpart AM—Ferrous Sulfate Production Subcategory [Reserved]

Subpart AN—Fluorine Production Subcategory

§ 415.400 Applicability; description of the fluorine production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of fluorine by the liquid hydrofluoric acid electrolysis process.

§ 415.401 Specialized definitions.

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include

contaminated non-process wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated nonprocess wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers, and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.402 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart AO—Hydrogen Production Subcategory

§ 415.410 Applicability; description of the hydrogen production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of hydrogen as a refinery by-product.

§ 415.411 Specialized definitions.

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR Part 401 shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated nonprocess wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated nonprocess wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.412 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except as provided for in Part 419 of this chapter (39 FR 16560).

Subpart AP—Hydrogen Cyanide Production Subcategory

§ 415.420 Applicability; description of the hydrogen cyanide production subcategory.

This subpart applies to discharges to waters of the United States and introduction of pollutants into publicly owned treatment works resulting from the production of hydrogen cyanide by the Andrussow process.

§ 415.421 Specialized definitions.

For the purposes of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" means hydrogen cyanide.

(c) The term "Cyanide A" means those cyanides amenable to chlorination and is determined by the methods specified in 40 CFR § 136.3.

§ 415.422 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AP—HYDROGEN CYANIDE

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	8.6	3.2
Cyanide A.....	0.10	0.021
Total Cyanide.....	0.65	0.23
pH.....	(?)	(?)

¹ Within the range 6.0 to 10.5.

§ 415.423 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

SUBPART AP—HYDROGEN CYANIDE

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
Cyanide A.....	0.10	0.021
Total Cyanide.....	0.65	0.23
Total Residual Chlorine.....	0.086	0.051

§ 415.424 [Reserved]

§ 415.425 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

SUBPART AP—HYDROGEN CYANIDE

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
TSS.....	8.6	3.2
Cyanide A.....	0.10	0.021
Total Cyanide.....	0.65	0.23
Total Residual Chlorine.....	0.086	0.051
pH.....	(?)	(?)

¹ Within the range 6.0 to 10.5.

§ 415.426 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as specified in § 415.424.

§ 415.427 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 40 CFR 125.30-125.32, any existing point source subject to this subpart must 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 are the same for TSS and pH as specified in § 415.422.

Subpart AQ—Iodine Production Subcategory

§ 415.430 Applicability; description of the iodine production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of iodine.

§ 415.431 Specialized definitions.

For the purpose of this subpart: (a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated non-process wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated non-process wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.432 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart AR—Lead Monoxide Production Subcategory

§ 415.440 Applicability; description of the lead monoxide production subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into treatment works which are publicly owned resulting from the production of lead monoxide.

§ 415.441 Specialized definitions.

For the purpose of this subpart: (a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include

contaminated non-process wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated non-process wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure or process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment; Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.442 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.443 [Reserved]

§ 415.444 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 40 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART AR—LEAD MONOXIDE

Pollutant or pollutant property	PSES effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Lead.....	2.0	1.0

Subpart AS—Lithium Carbonate Production Subcategory

§ 415.450 Applicability; description of the lithium carbonate production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of lithium carbonate by the Trona process and from spodumene ore.

§ 415.451 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean lithium carbonate.

§ 415.452 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using the Trona process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except that residual brine and depleted liquor may be returned to the body of water from which the process brine solution was originally withdrawn.

(b) Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart and using spodumene ore must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AS—LITHIUM CARBONATE

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 pounds) of product		
TSS.....	2.7 (¹)	0.90 (¹)

¹ Within the range 6.0 to 9.0.

Subpart AT—Manganese Sulfate Production Subcategory [Reserved]

Subpart AU—Nickel Sulfate Production Subcategory

§ 415.470 Applicability; description of the nickel sulfate subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into publicly owned treatment works resulting from the production of nickel sulfate from pure and impure raw materials.

§ 415.471 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean nickel sulfate.

§ 415.472 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AU—NICKEL SULFATE

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000-lb) of product		
Nickel (T).....	0.0060	0.0020
TSS.....	0.096	0.032
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.473 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to the subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT):

SUBPART AU—NICKEL SULFATE

Pollutant or pollutant property	Bat effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 pound) of product		
Copper (T).....	0.00074	0.00024
Nickel (T).....	0.00074	0.00024

§ 415.474 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART AU—NICKEL SULFATE

Pollutant or pollutant property	PSES Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Milligrams per liter (mg/l)		
Copper (T).....	1.1	0.36
Nickel (T).....	1.1	0.36

In cases where POTWs find it necessary to impose mass limitations, the following equivalent mass limitations are provided as an alternate: The limitations for copper (T) and nickel (T) are the same as specified in § 415.473.

§ 415.475 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS):

SUBPART AU—NICKEL SULFATE

Pollutant or pollutant property	NSPS effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 pound) of product		
TSS.....	0.096	0.032
Copper (T).....	0.00074	0.00024
Nickel (T).....	0.00074	0.00024
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.476 Pretreatment standard for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart

which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as specified in § 415.474.

§ 415.477 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 40 CFR 125.30-.32, any existing point source subject to this subpart must 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 are the same for TSS and pH as specified in § 415.472.

Subpart AV—Strong Nitric Acid Production Subcategory—[Reserved]

Subpart AW—Oxygen and Nitrogen Production Subcategory

§ 415.490 Applicability; description of the oxygen and nitrogen production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of oxygen and nitrogen by air liquification.

§ 415.491 Specialized definitions. [Reserved]

§ 415.492 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AW—OXYGEN AND NITROGEN

Pollution or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Kg/kg (or pounds per 1,000 lb) of product		
Oil and grease.....	0.0020	0.0010
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

Subpart AX—Potassium Chloride Production Subcategory

§ 415.500 Applicability; description of the potassium chloride production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of potassium chloride by the Trona process and by the mining process.

§ 415.501 Specialized definitions. [Reserved]

§ 415.502 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters, except that residual brine and depleted liquor may be returned to the body of water from which the process brine solution was originally withdrawn.

Subpart AY—Potassium Iodide Production Subcategory

§ 415.510 Applicability; description of the potassium iodide production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of potassium iodide.

§ 415.511 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this Chapter shall apply to this subpart.

(b) The term "product" shall mean potassium iodide.

§ 415.512 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART AY—POTASSIUM IODIDE

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
TSS.....	0.090	0.030
Sulfide.....	0.015	0.0050
Iron.....	0.015	0.0050
Barium.....	0.0090	0.0030
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

Subpart AZ—Potassium Permanganate Production Subcategory—[Reserved]

Subpart BA—Silver Nitrate Production Subcategory

§ 415.530 Applicability; description of the silver nitrate production subcategory

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into publicly owned treatment works resulting from the production of silver nitrate.

§ 415.531 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean silver nitrate.

(c) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated non-process wastewater, as defined below.

(d) The term "process wastewater pollutants" means pollutants present in process wastewater.

(e) The term "contaminated non-process wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such

contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.532 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART BA—SILVER NITRATE

Pollutant or pollutant property	BPT limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
Silver.....	0.0090	0.0030
TSS.....	0.069	0.023
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.533 [Reserved]

§ 415.534 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART BA—SILVER NITRATE

Pollution or pollutant property	PSES limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligram per liter (mg/l)	
Silver.....	1.0	0.5

Subpart BB—Sodium Bisulfite Production Subcategory

§ 415.540 Applicability; description of the sodium bisulfite production subcategory.

This subpart applies to discharges to waters of the United States and introduction of pollutants into publicly owned treatment works resulting from the production of sodium bisulfite.

§ 415.541 Specialized definitions.

For the purposes of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" means sodium bisulfite.

§ 415.542 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART BB—SODIUM BISULFITE

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Kg/kg (or pounds per 1,000 lb) of product	
TSS.....	0.32	0.080
COD.....	3.8	0.95
Chromium (T).....	0.0020	0.00063
Zinc (T).....	0.0051	0.0015
pH.....	(¹)	(¹)

¹ Within the range 6.0 to 9.0.

§ 415.543 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT): The limitations on COD, Chromium(T), and Zinc(T) are the same as specified in § 415.542.

§ 415.544 [Reserved]

§ 415.545 New source performance standards (NSPS).

Any new source subject to this subpart must achieve the following new source performance standards (NSPS): The limitations are the same as specified in § 415.542.

§ 415.546 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a

publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources (PSNS): The limitations are the same as specified in § 415.544.

§ 415.547 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 40 CFR 125.30-125.32, any existing point source subject to this subpart must 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 are the same for TSS and pH as specified in § 414.542.

Subpart BC—Sodium Fluoride Production Subcategory

§ 415.550 Applicability; description of the sodium fluoride production subcategory.

The provisions of this subpart are applicable to discharges and to the introduction of pollutants into publicly owned treatment works resulting from the production of sodium fluoride by the anhydrous neutralization process and by the silico fluoride process.

§ 415.551 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated non-process wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated non-process wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal

safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control, such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.552 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

§ 415.553 [Reserved]

§ 415.554 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 and 493.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources (PSES):

SUBPART BC—SODIUM FLUORIDE

Pollution or pollutant property	PSES effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Fluoride	50	25

Subpart BD—Sodium Hydrosulfide Production Subcategory [Reserved]

Subpart BE—Sodium Hydrosulfite Production Subcategory [Reserved]

Subpart BF—Sodium Silicofluoride Production Subcategory [Reserved]

Subpart BG—Sodium Thiosulfate Production Subcategory [Reserved]

Subpart BH—Stannic Oxide Production Subcategory

§ 415.600 Applicability; description of the stannic oxide production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of stannic oxide by the reaction of tin metal with air or oxygen.

§ 415.601 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated non-process wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated non-process wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product, byproduct or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.602 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

Subpart BI—Sulfur Dioxide Production Subcategory [Reserved]

Subpart BJ—Zinc Oxide Production Subcategory [Reserved]

Subpart BK—Zinc Sulfate Production Subcategory

§ 415.630 Applicability; description of the zinc sulfate production subcategory.

The provisions of this subpart are applicable to discharges resulting from the production of zinc sulfate.

§ 415.631 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "process wastewater" means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product. The term "process wastewater" does not include contaminated non-process wastewater, as defined below.

(c) The term "process wastewater pollutants" means pollutants present in process wastewater.

(d) The term "contaminated non-process wastewater" shall mean any water which, during manufacturing or processing, comes into incidental contact with any raw material, intermediate product, finished product,

by-product or waste product by means of (1) rainfall runoff; (2) accidental spills; (3) accidental leaks caused by the failure of process equipment, which are repaired within the shortest reasonable time not to exceed 24 hours after discovery; and (4) discharges from safety showers and related personal safety equipment: Provided, that all reasonable measures have been taken (i) to prevent, reduce and control such contact to the maximum extent feasible; and (ii) to mitigate the effects of such contact once it has occurred.

§ 415.632 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30-125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT): There shall be no discharge of process wastewater pollutants to navigable waters.

[FR Doc. 82-17445 Filed 6-28-82; 8:45 am]

BILLING CODE 6560-50