Claims must be submitted identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

(3) The Supplemental Statement of Data Confidentiality Claims must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

**§ 158.1001 Ingredients considered inert when used in antimicrobial products.**

The following substances are designated inert ingredients within the meaning of FIFRA section 2(m) when used in antimicrobial pesticide products:

| Substance | Uses |
|---|---|
| Acetone | Solvent. |
| Alkyl * amino betaine (46 percent $C_{12}$, 24 percent $3_{14}$, 10 percent $C^{16}$, 6 percent $C^{18}$, 7 percent $C_8$, 5 percent $C_{10}$. | Corrosion Inhibitor/Surfactant. |
| Alkyl monoethanolamide | Emulsifer. |
| Aluminum chloride | Detergent. |
| Aluminum hydroxybenzenesulfate sulfonate. | Emulsifer. |
| Aluminum powder | Filler. |
| Ammonium carbonate | Detergent. |
| Ammonium citrate | Sequesterant. |
| Ammonium lauryl sulfonate | Emulsifier. |
| Ammonium oleate | Detergent/Emulsifier. |
| Ammonium oxalate | Detergent. |
| Amyl acetate | Diluent. |
| Borax | Detergent. |
| Butyl alcohol, teritiary | Solvent/Odorant |
| Carbon | Carrier/Absorbent. |
| Castor oil | Emulsifier. |
| Citric acid | Sequesterant. |
| Diethanolamine dodecylbenzene sulfonate. | Detergent. |
| Dimethyl phthalate | Perfume. |
| Disodium monoethanolamine phosphate. | Emulsifier. |
| Dodecyl benzene sulfonic acid. | Detergent. |
| Essential oils | Perfume. |
| Ethanol (ethyl alcohol) | Solvent, except in tinctures or where sole or major active ingredient. |
| Ethanolamine | Emulsifier. |
| Ethanolamine dodecylbenzene sulfonate. | Detergent. |
| Ethoxylated lanolin | Ointment base. |
| Ethylenediamine | Emulsifier. |
| Ethylenediaminetetraacetic acid (including all salts and derivatives. | Sequesterant. |
| Fumaric acid | Sequesterant. |
| Gluconic acid | Buffer. |
| Isooctyl phenoxy polyethoxy ethanol. | Surfactant. |
| Isopropanol (isopropyl alcohol | Solvent, except in tinctures or where sole or major active ingredient. |
| Isopropyl myristate | Solvent. |
| Juniper tar | Odorant. |
| Lauryl alcohol | Detergent/Odorant. |
| Lauryl methacrylate | Emulsifier. |
| Limonene | Odorant/Perfume. |
| Magnesium chloride | Builder. |
| Magnesium lauryl sulfate | Detergent. |
| Magnesium silicate | Odor absorbent. |
| Menthol | Perfume. |
| Methanol (methyl alcohol) | Solvent, except in tinctures or where sole or major active ingredient. |
| Methyl ethyl ketone | Solvent. |
| Methyl salicylate | Perfume/Odorant. |
| Mineral oil, mineral seal oil or white mineral oil. | Lubricant. |
| Monoethanolamides of the fatty acids of coconut oil. | Emulsifier. |
| Monosodium phosphate | Emulsifier/Buffer. |
| Morpholine | Corrosion inhibitor. |
| Nonylphenoxypolyethoxyethanol.. | Suractant. |
| Octylphenol | Nonionic surfactant. |
| Oil of citronella | Perfume/Odorant. |
| Oil of eucalyptus | Perfume. |
| Oil of lemongrass | Perfume. |
| Oleic acid | Solvent. |
| Petroleum distillate, oils, hydrocarbons, also paraffinic hydrocarbons, aliphatic hydrocarbons, paraffinic oil. | Lubricant/Solvent. |
| Polyoxyethylene sorbitol, mixed ether ester of. | Emulsifier. |
| Polyvinylpyrolidone | Emulsifier. |
| Potassium bisulfate | Builder. |
| Polyvinylpyrrolidone | Emulsifier. |
| Potassium bisulfate | Builder. |
| Potassium carbonate | Detergent. |
| Potassium dodecylbenzenesulfonate. | Anionic detergent. |
| Potassium laurate | Emulsifier. |
| Potassium myrisate | Emulsifier. |
| Potassium *N*-(*s*-(nitroethyl) benzyl) ethylenediamine. | Emulsifier. |
| Potassium phospatae, tribsic | Sequesterant. |
| Potassium ricinoleate | Emulsifier. |
| Potassium toluene sulfonate | Detergent. |
| Potassium xylene sulfonate | Detergent. |
| Propanol (propyl alcohol) | Solvent, except in tinctures or where sole or major active ingredient. |
| Soap | Detergent. |
| Sodium acetate | Buffer. |
| Sodium alkyl (100 percent $C^9$): benzenesulfonate.. | Detergent. |
| Sodium bicarbonate | Detergent. |
| Sodium carbonate | Detergent. |
| Sodium chloride | Builder. |
| Sodium decylbenzene sulfonate. | Detergent. |
| Sodium diacetate | Sequesterant. |
| Sodium dihydroxyethylglycine | Chelate/Buffer. |
| Sodium disopropyinaphthalene sulfonate. | Detergent. |
| Sodium di (monoethanolamine) phospate. | Emulsifier. |
| Sodium dodecylbenzene sulfonate (May be active as a sanitizer in dishwashing formulations). | Detergent. |
| Sodium dodecyl diphenyl oxide sulfonate. | Perfume. |
| Sodium glycolate | Sequesterant. |
| Sodium laurate | Detergent. |
| Sodium N-lauroylsarcosinate | Detergent. |
| Sodium lauryl sulfate | Detergent. |
| Sodium metasilicate | Detergent. |
| Sodium *N*-methyl-*N* oleoyl taurate. | Emulsifier. |
| Sodium mono and dimethyl naphthalene sulfonate. | Detergent. |
| Sodium oleate | Emulsifier. |
| Sodium phosphate | Emulsifier/Buffers. |
| Sodium salt of Turkey Red Oil | Emulsifier. |
| Sodium sesquicarbonate | Detergent. |
| Sodium silicate | Detergent. |
| Sodium sulfate | Detergent. |
| Sodium sulfonated oleic acid | Emulsifier. |
| Sodium thiosulfate | Builder. |
| Sodium toluene sulfonate | Detergent. |
| Sodium tripolyphosphate | Sequesterant. |
| Sodium xelene sulfonate | Detergent. |
| Tetrapotassium pyrophosphate. | Sequesterant. |
| Tetrasodium pyrophosphate | Emulsifier. |
| 1,1,1,-Trichloroethane | Diluent. |
| Triethanolamine | Emulsifier. |
| Triethanolamine dodecylbenzene sulfonate. | Detergent. |
| Triethanolamine laurate | Emulsifier. |
| Triethanolamine lauryl sulfate | Emulsifier. |
| Triethanolamine myristate | Emulsifier. |
| Triscopropanolamine | Emulsifier. |
| Triethanolamine | Emulsifier. |
| Trisodium phosphate | Detergent. |
| Turkey red oil | Emulsifier. |
| Undecylenic acid | Perfume. |
| Xylene | Solvent. |
| Zirconium oxide | Dye. |

## PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

### Subpart A and E—[Removed]

4. By removing Subparts A and E of Part 162.

[FR Doc. 84-25226 Filed 9-25-84; 8:45 am]

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Part III

# Environmental Protection Agency

40 CFR Parts 156 and 167

Labeling Requirements for Pesticides and Devices; Proposed Rule

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 156 and 167

[OPP-30052; FRL 2604-1(a)]

### Labeling Requirements for Pesticides and Devices

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to revise and expand its regulations for the labeling of pesticide products and devices under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA). The proposed regulation states the labeling requirements for pesticides required to be registered and provides recommendations for labeling when no requirement is imposed. Requirements are also proposed for pesticide products whose labeling is subject to Agency regulation under the misbranding provisions of the FIFRA, but which are not required to be registered. This subpart would describe the requirements for the format and placement of the label, and the relationship of its various elements. It would also establish requirements for the content of pesticide labels, the scientific criteria, if any, on which specific requirements are based, and, when necessary, the specific wording to be used. The Agency believes that this revision will provide for pesticide producers a comprehensive description of pesticide labeling requirements, and will result in better quality pesticide labeling for users.

**DATE:** Written comments on this proposed rule should be submitted on or before December 26, 1984. Mark comments with the notation OPP-30052.

**ADDRESS:** Submit written comments to: By mail: Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental protection Agency, 401 M St., SW, Washington, D.C. 20460

In person, bring comments to: Rm. 236, CM#2, 1921 Jefferson Davis Highway Arlington, VA.

Information submitted in any comment concerning this proposed rule may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submited for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in Rm. 236 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Jean M. Frane, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location and telephone number: Rm. 1114, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-0592).

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

### *A. Authority*

This part would establish comprehensive regulations for the form and content of pesticide product labeling, and is issued under the authority of sections 2, 3(c), 5, 6, 7, 9, 10, 12, 17, 18, 19, and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA" or "the Act"), 7 U.S.C. 136 through 136y. It would apply both to pesticides required to be registered and to pesticides not subject to registration requirements but for which the Agency has authority to regulate labeling.

The statutory standard that is the basis for Agency regulation of pesticide labeling is contained in section 2(q) of FIFRA, which defines a "misbranded" pesticide and enumerates specific labeling deficiencies that constitute misbranding. The regulations interpret and elaborate upon the statutory standard.

The Agency is empowered to enforce its labeling requirements pursuants to its authority to regulate pesticide distribution and sale. FIFRA sec. 3 requires that a pesticide be registered prior to distribution and sale. As a prerequisite to registration, the labeling of the pesticide must comply with the requirements of the Act. Failure to comply with the labeling requirements may result in a denial of an application for registration or may provide grounds for cancellation of the registration of the pesticide under FIFRA sec. 6.

In addition, section 12(a)(1) (E) and (F) of FIFRA provide that it is unlawful to distribute or sell a pesticide or device that is misbranded. (The Act does not define a "misbranded" device, but EPA interprets the pesticide misbranding provisions to apply to devices.)

The Agency has issued regulations under section 5 of FIFRA establishing labeling requirements for pesticides distributed and sold under experimental use permits. These labeling requirements are currently set out in 40 CFR 172.6. This part includes room for the section 5 labeling regulations should the Agency decide to transfer them to this part at a future time.

The regulations in 40 CFR Part 166 for emergency exemptions do not currently include labeling requirements. Section 156.112 of this part establishes requirements for products shipped in accordance with an emergency exemption.

### B. Background

In the **Federal Register** of July 3, 1975 (40 FR 28242), EPA issued final regulations ("the 1975 regulations") for the registration and classification of pesticides. These regulations, codified as 40 CFR Part 162, Subpart A, included requirements for the labeling of registered products in § 162.10.

Since the 1975 regulations on registration were published, FIFRA has been amended three times, in 1975, 1978, and 1980. The 1978 amendments included provisions directly affecting labeling, and others having broad implications for labeling:

1. Unregistered pesticides produced for export only are now required to bear a statement that they are not registered in the United States (FIFRA sec. 2(q)(1)(H)).

2. FIFRA sec. 2(ee) was added to define the term "to use any registered pesticide in a manner inconsistent with its labeling." It is a violation of the law to use any registered pesticide in a manner inconsistent with its labeling. That section expressly excludes certain types of use from the definition.

3. FIFRA sec. 3(c)(5) was amended to permit the Administrator to register a pesticide without determining whether its composition is such as to warrant the proposed claims for it. The Agency issued conditional registration regulations, which were published in the **Federal Register** of May 11, 1979 (44 FR 27932), that waived the requirement to submit efficacy data for all but public health pest claims and new uses of chemicals whose registrations have been cancelled, suspended, or placed under special review. The Agency issued a rule, published in the **Federal Register** of July 26, 1983 (48 FR 34000), that extended the efficacy data waiver to additional pesticide products. Under the waiver, the Agency no longer reviews efficacy data upon which use directions are based for new products or new uses of existing products. Without this initial product performance data, the Agency is compelled to monitor more closely the content of use

directions on labels. Label use directions directly relate to the potential for exposure from the use of pesticides. If a pattern of inaccurate, outdated, or ambiguous use directions is determined to be a major problem, the Agency will require the submission of efficacy data on an individual basis or for a group of common products.

In the **Federal Register** of June 25, 1975 (40 FR 26802), EPA issued proposed guidelines describing data and labeling requirements for pesticides. These were intended to supplement the labeling regulations mentioned earlier in the use directions area. The Agency proposed to add a new section pertaining to labeling, focusing primarily on requirements for use direction labeling for various types of products. In response to the 1975 proposal, over 80 sets of comments were received relating directly to the labeling portion. These comments have been considered in drafting this new subpart. However, due to the broad expansion in scope of this new proposal and the extensive restructuring that has occurred in its development, some of the comments no longer appear pertinent. EPA believes that the comments have been adequately considered, but if not, commenters are invited to reiterate their comments at this time. In preparing the final regulations EPA will address issues raised by commenters.

A Label Improvement Program has been initiated to bring older registered products into compliance with the requirements of current § 162.10. In addition, labeling changes, including many in this proposal, may be required on a case-by-case basis at any time an application for registration, amended registration or reregistration is submitted, or if the Agency issues a notice of intent to cancel the registration of a product.

### *C. Scope and Organization of Part 156*

As noted previously in Unit I.A, Authority, Part 156 would prescribe, for all pesticides for which the Agency has authority to regulate labeling, the form and contents of the label, and the relationship of label components. In the context of registration, where data requirements are the basis for labeling statements, this part would relate label requirements and criteria to the data supporting registration.

Part 156 would not specify the circumstances when labeling must be submitted or revised, the responsibility of registrants and producers to maintain label accuracy and integrity, or the administrative and procedural requirements of submission, Agency review, and approval of labeling. Finally, it would not address the legal or enforcement consequences of failure to adhere to these requirements. These aspects of labeling are addressed in procedural regulations currently found in 40 CFR Part 162, Part 166, and Part 172. Elsewhere in today's **Federal Register**, a related proposal to revise and renumber Part 162 is being issued.

This proposal primarily addresses labeling of products required to be registered, since the most extensive labeling requirements are imposed on such products. Section 3(c) (5) of FIFRA sets forth the statutory requirement for registration with respect to labeling, as follows:

> The Administrator shall register a pesticide if he determines that, when considered with any restriction imposed under subsection (d)—* * * (B) its labeling and other material required to be submitted comply with the requirements of this Act; * * *.

1. The requirements for labeling that "complies with the requirements of the Act" are encompassed within the statutory definition of misbranding, found in FIFRA sec. 2(q). This definition establishes as misbranded a pesticide that, among other things, does not bear a label containing:

a. The name of the product;

b. The name and address of the producer, registrant, or person for whom produced;

c. A net weight statement;

d. An ingredients statement;

e. A use classification;

f. Registration and establishment numbers assigned to the product and producing establishment, respectively; or

g. Use directions.

Furthermore, required labeling statements must be prominent and conspicuous and may not be false or misleading. It is important to note that, although many of the misbranding requirements relate only to registered products, the term "misbranded" applies to any pesticide, whether subject to registration or not (and, by extension, to devices).

2. In addition to labeling requirements for registered products, Part 156 proposes labeling requirements for pesticides not required to be registered and for devices. Because these requirements often parallel those for registered products, they are cross-referenced except where differences exist. The following classes of products would be included:

a. Products shipped between establishments operated by the same producer.

b. Products intended solely for export.

c. Products shipped under an emergency exemption.

d. Products shipped for disposal under FIFRA sec. 19.

e. Devices.

Subpart A of these proposed regulations contains general requirements that apply to all or most products. Subpart B describes product identification requirements, Subpart C precautionary statements, and Subpart D use directions and restrictions. Subpart E proposes requirements for specialized labeling situations. Subpart F proposes requirements for products not subject to registration. Subpart P prescribes performance standards and resulting labeling reguirements for antimicrobial products. If labeling requirements are in the future prescribed for other specific types of products they would be located in subparts beyond Subpart P.

### *D. Relation to Current Labeling Regulations*

Labeling requirements for registered products are currently prescribed in § 162.10 of the registration regulations (40 CFR Part 162). Requirements for the labeling of products to be used under an experimental use permit are contained in 40 CFR Part 172. Labeling requirements for other pesticides and devices are not currently prescribed by regulation.

This part is intended to serve as the principal source of labeling requirements for pesticide products. The Agency is revising its procedural regulations in Part 162 (see the related document being proposed today), and will retain and amplify in that part provisions concerning the submission, review, and approval of labeling.

## II. Major Provisions of This Proposal

### *A. Format of Label*

The Agency believes that standardizing the placement of certain elements of the label makes label information readily identifiable, thereby encouraging users routinely to read and observe label directions and precautions. For the most part, this proposal would retain the format requirements of the 1975 regulations with respect to required placement of label elements and grouping of common or related elements.

With respect to contrast, the Agency would require that the label text contrast with the background with respect to color, and would recommend the use of dark-colored text on a lighter background. The Agency would reserve the right to reject color combinations that are not clearly contrasting. Two

additional clarifying requirements have been added in this section:

1. If the container is transparent, the color of the label text must clearly contrast with the contents of the container, rather then the container itself; and

2. When the product label is required to bear the word POISON in red, surrounding text may not be in red.

The Agency proposes in this revision to convert its type size requirements from U.S. units to metric units. Section 156.10(c) expresses label dimensions in metric units and letter height in absolute millimeters rather than "points." Specification in absolute units is in keeping with the requirements of other agencies having labeling statutes, such as the Federal Hazardous Substances Act and the Fair Packing and Labeling Act. The metric equivalents are based on the established conversion factors of 72 points to one inch and one inch to 25.4 millimeters, rounded to the nearest one-half millimeter. The following table shows the differences in the proposed type size requirements compared to those in the current regulations.

TABLE A—TYPE SIZE REQUIREMENTS FOR PESTICIDE LABEL TEXT IN PROPOSED PART 156 IN METRIC UNITS

| Square inch (current requirement) | Approximate square centimeters (proposed requirement) | Type size requirement for— | | | |
|---|---|---|---|---|---|
| | | Signal word and restricted use statement | | Child hazard warning | |
| | | Current | Proposed | Current | Proposed |
| Column [1](1) | (2) | (3) | (4) | (5) | (6) |
| <5 | <30 | 6 | 2.0 | 6 | 2.0 |
| >5-<10 | >30-<60 | 10 | 3.5 | 6 | 2.0 |
| >10-<15 | >60-<100 | 12 | 4.0 | 8 | 3.0 |
| >15-<30 | >100-<200 | 14 | 5.0 | 10 | 3.5 |
| >30-<60 | >200-<400 | 18 | 6.5 | 12 | 4.0 |
| >60 | >400 | 24 | 8.5 | 18 | 6.5 |

[1] Only colums 2, 4, and 6 appear in Table 1 of § 156.10

Further, the Agency proposes to discontinue the requirement that the heading for the Storage and Disposal statement appear in the same type size as the required for the child hazard warning. Since the storage and disposal heading is but one of many headings required or used on the label, there appears to be no logical reason to single it out for particular type size requirements. Instead, EPA proposes to require that all required headings, including that for the storage and disposal instructions, be distinguished from text by use of a contrasting color, larger type size, different type face, or other means of ensuring prominence.

Finally, the Agency would like comment on the possibility of permitting registrants to provide (and segregate on the label) information that was not required by regulations or by the Agency. The registrant could in this way provide additional information to users, provided that it is not misleading or inconsistent with other label statements. A registrant also could choose to voluntarily restrict the product's use in ways not required by the Agency. Although such statements could not be enforced under the misuse provisions of FIFRA sec. 12, users and State pesticide enforcement officials could distinguish those restrictions which the Agency explicity requires from those that it suggests or recommends, or that are registrant-imposed.

*B. Use of Symbols*

Section 156.10 of these regulations would permit, but would not require, the use of graphic symbols on pesticide labels as an accompaniment to the labeling text.

The Agency recognizes that symbols can be a valuable tool in communicating information on chemical characteristics and hazards to illiterate people, or those who may not speak or read English as their primary language. Moreover, EPA is aware that numerous symbol systems have been devised both by organizations and individual countries to facilitate communication of hazard information in international commerce. Nevertheless, EPA believes it would be inappropriate to endorse (or require the use of) any single symbol system at this time. If, in the future, standardization of international labeling criteria and requirements (a goal that the Agency supports) is achieved through international cooperation, and a unified set of symbols developed, the Agency may adopt and prescribe the use of such symbols on pesticide labels.

The Agency is also considering, and would like specific comment on, a system that would use colored bands at the bottom of the label to identify the acute toxicity level of the product. Such a system has been recommended for use by South American, Central American, and Caribbean nations by the Plant Protection Directors of those nations, at a regional consultation on the Harmonization of Registration and Labeling sponsored by the Inter-American Institute for Cooperation on Agriculture. The color band scheme would use the colors red, yellow, blue and green (in that order from highest to lowest toxicity) as a band along the base of the label, equal to 15 percent of the width of the label. The colored band would be supplemented by wording within the band indicating the toxicity category designation of the product, signal words, and, if applicable, the skull and crossbones symbols.

*C. Product Identification*

Section 156.20 would require that the name of a pesticide product appear on the front panel of the label, would state requirements relating to unique and duplicative names, and would specify naming practices considered false or misleading.

Section 156.22 would require that a product label indicate the broad pesticidal functions of the product, so that a purchaser unfamiliar with pesticides will not knowingly purchase a product that will not serve his needs. Most product labels already provide this information in one or another acceptable form.

Section 156.24 would establish requirements with respect to the name and address appearing on the label. The Agency is proposing two modifications in the requirements from those currently in effect. Section 162.10 of the 1975 regulations permits the name and address on the label to be that of the "producer, registrant, or person for whom produced." Since the purpose of having a name and address on a pesticide label is to enable the user to direct questions or problems to the person responsible for the product, the Agency believes that the name of the producer on the label is not sufficient for this purpose. Accordingly, this section would require that the name appearing on the label be that of the registrant (or distributor). Nothing would preclude the registrant or distributor from also including the name of the producer of the product if he so desires. A clarification has also been proposed that a foreign registrant who is required to have a U.S. agent for administrative and correspondence purposes, must include the name and address of the registrant and not the agent on the label.

Section 156.36 would prescribe requirements pertaining to the net

contents statement on the label. These regulations propose changes in the requirements for the declaration of net contents, so that pesticide labels conform more closely to those of non-pesticide products. The following revisions are proposed:

1. Elimination of current requirements with respect to the form of the net contents statement. The net contents may be expressed in any reasonable manner, provided that the units chosen are appropriate to the size of the package. Products in compliance with the requirements of the Fair Packaging and Labeling Act, as found in 16 CFR Part 500, would be considered to be in compliance with the requirements of FIFRA.

2. Addition of requirements (consistent with those in 16 CFR Part 500) for the declaration of net contents on the outer container of a multi-unit package, whose unit packages are not intended for separate retail sale. Currently, there are no specific requirements for declaring the number or net weight of the individual unit packages, although many products bear such statements.

3. A provision permitting, but not requiring, metric units in lieu of, or in precedence to, U.S. units. Although the use of metric units in both labeling and packaging is voluntary, their use is strongly encouraged by the Agency when practicable.

*D. The Ingredients Statement*

Under the provisions of 40 CFR 158.120, proposed in the **Federal Register** of November 24, 1982 (47 FR 53192), an applicant would be required to determine and submit to the Agency the upper and lower limits on the amount of each active ingredient present in his product. Since the lower certified limit would actually be present in the product only a small percentage of the time, the Agency proposes in this subpart that the label declaration of active ingredient percentage be the amount of active ingredient found in a typical sample of the product (the "normal concentration"). The nominal concentration will always be within the stated certified limits for the active ingredient.

Use of the nominal concentration as the label declaration of active ingredients would not represent a change in Agency policy. Current regulations require that the lowest percentage which may be present be stated, within the limits of good manufacturing practice. The certified limits required for each active ingredient are intended to encompass the "good manufacturing practice" variations referred to in current regulations, so that the lower certified limit represents the lowest amount that may be present. The lower certified limit would be used as the enforceable lower limit on product composition for purposes of FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect they will be routinely provided to States for enforcement purposes, since the nominal concentration appearing on the label will not represent the enforceable composition for purposes of section 12(a)(1)(C).

The Agency also proposes to establish an order or precedence of common names used in the ingredients statement. Previously, the only common name acceptable on the label was that approved by the American National Standards Institute (ANSI). If there was no ANSI name the chemical name alone was to be used. Many older pesticides do not have ANSI common names. The Agency believes that the length and complexity of most chemical names prevents users from recognizing and becoming familiar with those pesticides. Therefore, the proposal would permit the use of common names established by the International Standards Organization (ISO), the British Standards Institute (BSI), or an established technical association in the absence of an established ANSI common name. New pesticides never before registered would be required to have a common name for use on the label.

*E. Elimination of Mandatory Expiration Dating*

The 1975 regulations required that, if a product's composition was known to change significantly after manufacture, the label must bear an expiration date after which the product could not be sold or used. Under this proposal, a registrant would no longer be required to use an expiration date. However, the product would have to meet all composition claims while in channels of trade, and registrants might wish to use an expiration date on the label to limit potential enforcement action for product deterioration.

Anticipated product deterioration would also affect the label directions for use. In developing use directions for a product that degrades rapidly, the registrant should make allowances for any changes in efficacy resulting from the constantly decreasing percentage of active ingredient. Many products known to deteriorate are used against pests of public health significance, where product ineffectiveness due to inadequate label dosages could have serious health consequences. Proposed § 156.72(i)(6) would require that the use directions instruct the user how to compensate for the lower level of active ingredient present at the time of use, such that the user could ascertain the correct dosage and proper use conditions at any time during which the product may be legally used.

*F. Toxicity Category Revisions*

EPA is proposing in this part to revise the Toxicity Category criteria for dermal toxicity and for eye irritation potential, to clarify the wording of the Toxicity Category criteria for dermal irritation, and to make the inhalation criteria consistent with the test methods advocated by the Registration Guidelines.

The Agency is proposing to revise the criteria for Category IV toxicity for dermal exposure. The 1975 regulations established a lower limit for Category IV dermal toxicity as 20,000 mg/kg. Since that time, the Agency has become aware that in many cases such a high level of test material cannot reasonably be achieved on the skin of the test species. Consequently, a registrant who believes that his product is in Toxicity Category IV cannot easily demonstrate that fact through testing, and his product is assigned to Toxicity Category III. In its Registration Guidelines, the Agency has recommended that dermal toxicity testing be conducted with 5000 mg/kg of test substance, the maximum that can realistically be achieved. Accordingly, the Agency is proposing to assign products to dermal Toxicity Category IV based on the 5000 mg/kg test level.

EPA is also proposing to add to the dermal irritation criteria clarifying language intended to provide better guidance on the application of the criteria. The addition of clarifying language would not in any way increase or decrease the stringency of the criteria.

The Agency further proposes to change the eye irritation criteria. Until 1975, the Agency had no published eye irritation criteria nor any Toxicity Categories assigning signal words for eye irritation potential. Unpublished criteria were applied to products for the purpose of labeling. These criteria were subsequently adopted in the Agency's 1975 regulations (40 CFR 162.10(h)(1)),

and were established on the basis of the best information available at the time.

In 1976, the Consumer Product Safety Commission, which administers the Federal Hazardous Substances Act, requested that the National Academy of Sciences (NAS) revise its 1964 document entitled "Principles and Procedures for Evaluation the Toxicity of Household Substances," commonly known as the NAS 1138 publication. In conjunction with that revision, the Soap and Detergent Association submitted a study on toxicity test procedures that included a comprehensive study [1] on eye irritation effects of substances known to be injurious to the eye. One of the more significant conclusions of the study was the following:

> For adequate evaluation of the effects produced by introducing chemicals into the eyes of animals, the observation period must extend up to three weeks. Some injuries may not be evident until after 3 days have passed, and many lesions undergo significant healing within 21 days.

The study proposed a classification scheme for eye irritation severity based on a three-week observation period, and recommended that the reversibility of the effects within the period be considered a factor in classifying substances. The proposed scheme defines four categories of eye irritation encompassing: (1) Corrosive or severe irritation; (2) substantial harm, but reversible within 21 days; (3) moderate irritation reversible in less than 7 days; and (4) essentially inconsequential effects. The results of this study were endorsed and adopted in the revised NAS 1138 publication issued in 1977.[2]

In 1979, EPA adopted the eye criteria of the NAS as one of the determinants of whether a pesticide product should be packaged in child-resistant packaging as required by 40 CFR 162.16, and stated its intention to incorporate these eye criteria into the registration regulations defining Toxicity Categories. See the **Federal Register** of March 9, 1979 (44 FR 13022). Accordingly, the Agency is proposing in Table 1 of § 156.42 new Toxicity Categories for eye irritation.

This revision might affect products that are assigned to Toxicity Categories I and II. Proiducts currently in Categories III and IV would not be affected, since the criterial for those categories are essentially unchanged.

Note also that the term "corneal opacity" which is used in the current regulations would be replaced with the term "corneal involvement." This revision recognizes that corneal opacity is only one facet of corneal injury and healing of the injured tissue.

In conjunction with the change in criteria, EPA would incorporate into the hazard warnings for the new categories a description of the actual degree of severity of the effects to be expected, and so proposes to included in Table 4 of § 156.52(b) language that reflects the category terminology adopted in the NAS 1138 publication.

As a third revision, EPA is proposing to revise inhalation criteria to reflect the test methods recommended in the Registration Guidelines. Current labeling categories provide for the following Toxicity Categories:

Category I—$LC_{50}$ up to 0.2 mg/l
Category II—$LC_{50}$ from 0.2 mg/l through 2 mg/l
Category III—$LC_{50}$ from 2 mg/l through 20 mg/l
Category IV—$LC_{50}$ greater 2 than 20 mg/l

Exposure durations are not specified; however, in practice these concentrations have been based on one-hour exposures and the exposure levels have been based on a calculated concentration. The Registration Guidelines in Subdivision F recommend 4-hour exposures and actual concentration levels, for the following reasons:

1. One-hour exposures do not allow time for equilibration of the atmospheres within the chambers, and the concentrations within the chambers are much lower than indicated by the nominal concentration estimates.

2. The nominal concentration, especially for aerosols, is not an accurate measure of the actual inhalable concentration, and is often off by a factor of 10 to 100 (or higher).

3. The short 1-hour exposure does not readily lend itself to adequate sampling of the atmospheres for concentrations and particle sizes. Moreover, the four-hour exposures are more conservative in evaluating possible acute exposures in humans.

Most inhalation exposures obey Haber's Law, which states that the product of the exposure time and the cocentration is a constant. Therefore the proposal, in defining a 4-hour exposure period instead of the 1-hour period commonly used in the past, also reduces the Toxicity Category criteria by a factor of four. Applicants who choose test methods using an exposure time other than 4 hours should be aware that the inverse relationship of exposure concentration and exposure time will be maintained in applying the criteria, i.e., if testing is conducted for two hours, the criteria for the categories will be doubled.

The Agency is considering ways in which it might establish a chronic effects labeling scheme. EPA acknowledges the difficulties inherent in addressing chronic effects, for which quantitative criteria are often not feasible or self-evident. Additional difficulties may arise in attempting to translate those effects into a practical labeling scheme. EPA efforts are still in a formative stage, and the Agency would like comment on the feasibility of chronic effects labeling, possible ways of implementing a scheme within the framework of FIFRA, and possible language that could be used to convery accurately the nature and risks of chronic effects.

*G. Statement of Practical Treatment*

Section 156.48 would require that a statement of practical treatment appear on the labels of most pesticide products. Products in Toxicity Categories I, II, and III by any route of exposure would be required to bear information on measures that can or should be taken when excessive exposure occurs. Separate information would be required for those treatments that the average person can undertake, and those that can be provided only by medical personnel or physicians. A "Note to Physician" would be mandatory for products in Toxicity Category I, or products possessing characteristics for which specific medical treatment is essential or singularly beneficial.

Practical treatment statements for Toxicity Category I routes of exposure are currently required to appear on the front panel of the label, preferably contained in a blocked paragraph. The agency woud prefer that all practical treatment statements appear on the front panel, but since label space may not always permit this ideal placement, practical treatment statements for Categories II and III could be placed with the general precautionary statements on a side or back panel of the label. In this case, a referral statement on the front panel would be required. The heading "Practical Treatment" or "First Aid," would be permitted, but the paragraph could not be titled "Antidote" unless a specific antidote is available. Typical and currently recommended practical

[1] Green, W.R., J.B. Sullivan, R.M. Hehir, and L.G. Scharpf. 1976. A systematic comparison of chemically induced eye injury in the albino rabbit and rhesus monkey. In Appendix C of: Submission to the National Academy of Sciences by the Soap and Detergent Association on Toxicity Test Procedures, with Appendices A–F. Soap and Detergent Association, Washington, DC.

[2] Committee for the Revision of NAS Publication 1138, Committee on Tox., Nat. Res. Council. 1977. Principles and Procedures for Evaluating the Toxicity of Household Substances. Pp. 1–9, 23–55. Prepared for the Consumer Product Safety Commission. National Academy of Sciences, Washington, D.C.

treatment statements are provided in Tables 1 through 5 of § 156.52.

*H. Labeling Requirements for Inert Ingredients*

FIFRA authorizes EPA to regulate all ingredients used in pesticide products, including inert ingredients that are not in themselves pesticidally active. These include solvents, emulsifiers, defoaming agents, perfumes and fragrances, propellants, diluents of all sorts, and similar ingredients whose presence in the formulation is ancillary to its pesticidal function. The definition in FIFRA section 2(m) of such ingredients as "inert" is intended only to distinguish them from those that are pesticidally active, and in no way signifies that they are toxicologically or chemically inert. Inert ingredients may or may not be hazardous by themselves, or in combination with other ingredients.

Because the identity of an inert ingredient is protected from disclosure by FIFRA sec. 10(d)(1)(C), a prerequisite for labeling identification of such ingredients is that the Agency make a finding that "disclosure is necessary to protect against an unreasonable risk of injury to health or the environment." EPA believes that this criterion is clearly met when the presence of an inert ingredient contributes significantly to the overall acute hazard of the product.

Required label statements would take the form of identification of the ingredient, precautionary statements to address the particular hazard of the inert ingredient, or more commonly, both. Table 1 of § 156.50 lists specific inert ingredients and proposed label requirements for products containing them. The table would be expanded to include other inert ingredients as the need arises.

The Toxic Substance Control Act (TSCA) regulates chemicals that are also used as inert ingredients in pesticide products. If data development is required under TSCA for a chemical that is an inert ingredient in pesticide products, such data may serve as the basis for label statements under FIFRA. If labeling regulations are issued under sec. 6 of TSCA, the Agency would consider applying those requirements to chemicals used as pesticide inert ingredients to the extent possible within the framework and authority of FIFRA.

*I. Human Hazard Precautionary Statements*

Section 156.52 proposes requirements for human hazard precautionary statements, and their location and format, if applicable. The section consists primarily of a series of tables specifying precautionary statements pertaining to:

(1) Signal word; (2) precautionary measures to avoid or reduce the possibility of injury; and (3) instructions on practical treatment or other remedial steps to take if exposure occurs.

The statements and format requirements proposed in this section are largely unchanged from those in the 1975 regulations in 40 CFR 162.10(h)(2)(i), but have been expanded and are better organized. Practical treatment measures recommended by the Agency have been added.

The statements are provided as a guide, but are those that would be commonly required for pesticide products in the prescribed Toxicity Categories. Because it is impossible to prescribe in these Tables exact statements for all combinations of ingredients, formulation types, and uses, the statements would be considered the minimum acceptable ones, and not inclusive of all statements that might be required. The need for additional precautionary statements or modified ones would be determined on a case-by-case basis.

A new § 156.52(c) has been added that would require a statement concerning respirator use for a pesticide that is highly toxic or toxic (Category I or II) by the inhalation route of exposure. The respirator requirement has been applied on a case-by-case basis for several years, but without being linked to specific toxicity criteria. EPA now believes that a required statement is necessary in this regard. To ensure that respirators provide adequate protection, only respirators approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health for pesticide use could be recommended on the label.

*J. Environmental Hazard Precautionary Statements*

Section 156.55 proposes requirements for environmental hazard statements (non-target species such as fish, aquatic invertebrates, wild mammals, birds, and beneficial insects) most of which were originally established in the 1975 regulations. Retaining the basic criteria and toxicity statements prescribed in present 40 CFR 162.10(h)(2)(ii), this section would prescribe acute toxicity criteria for labeling pertaining to honeybees, based on data that would be submitted in accordance with proposed 40 CFR 158.155 (Non-target insect data requirements). In addition, in the intervening period since the 1975 regulations were published, the Agency's responsibilities under the Endangered Species Act of 1975 have been carefully spelled out in regulations issued by the Department of the Interior (50 CFR Part 402). EPA has instituted a process for evaluating hazards to endangered species in consultation with the Departments of the Interior and Commerce—a process that may result in labeling statements of a restrictive nature. Finally, recent Agency labeling requirements have been shifted away from non-specific label statements that rely on interpretation by the user. It is increasingly clear, both from a legal and an enforcement standpoint, that label statements must contain a precise description of parameters that define the permitted use of the product.

Environmental hazard statements are of three types: those where explicit wording can be prescribed for all or most outdoor use products; those which derive primarily from the known toxicity of the active ingredient in outdoor use products based on testing that would be required by proposed 40 CFR 158.145 and 158.155; and those which are dependent on an evaluation of the product's hazards, use patterns, potential exposure, and other factors. These last generally take the form of use restrictions, and are generally prescribed on a case-by-case basis. Refer to § 156.76, Restrictions on Use.

The testing requirements of 40 CFR Part 158 allow the Agency to determine whether criteria for labeling statements of toxicity to fish, birds and mammals, aquatic invertebrates and honeybees are met. The 1975 regulations contained the same criteria concerning toxicity to fish, birds and mammals as are proposed here. The aquatic invertebrate criterion is new. Subdivision L of the Registration Guidelines describes recommended data protocols for beneficial insects (pollinators, aquatic insects, and predators), the honeybee being of primary concern. Of the beneficial insects, acute toxicity data are generally available only for the honeybee. Data requirements for other non-target insects are at a formative stage; therefore, toxicity categories and label statements prescribed by this part are limited to honeybees. As data requirements for other non-target insects are developed, additions and modifications to this part will be made to accommodate required labeling.

The Agency also proposes to modify the effluent discharge statement for products having uses that result in effluent discharges either directly into surface waters of the U.S. or indirectly into a sewer system. Examples of such products are those for formulating use, industrial treatment, cooling towers,

pulp and paper mills, and leather tanning operations. Point source discharges (such as from a single site) are generally governed by the issuance of a National Pollutant Discharge Elimination System (NPDES) permit that may regulate the level or type of pollutants allowed to be discharged. Sewage treatment facilities that discharge are also required to have NPDES permits.

Since 1977 the Agency has required a statement prohibiting discharge into U.S. surface waters except in accordance with an NPDES permit. This language was used in the belief that pesticides contained in such discharges would be considered in setting the standards for each individual permit, or that in the absence of specific language in the permit, no discharge was permitted. This is apparently not so. A common misunderstanding of the NPDES system is that substances not mentioned in permits are not permitted to be discharged. In fact, the opposite is true: If a substance is not specifically mentioned in the NPDES permit, it may be discharged without limitation. Therefore the 1977 language would in most cases result in no control over the discharge of any particular pesticide.

The proposed language would not require that an NPDES permit set quantitative limits on the amount or concentration of pesticide that could be discharged in an effluent. Other general controls, such as good management practices, may be sufficient. Therefore, the label statement merely requires that the pesticide be "identified and addressed" in the NPDES permit.

Facilities that discharge pesticide-containing effluent to a sewer system are not required to obtain NPDES permits (the sewer system authority must obtain the permit). Therefore the label statement that applies to direct discharge operations is not appropriate for these indirect dischargers. Nonetheless, pesticides from industrial sources can seriously disrupt the operation of biolagical wastewater treatment plants by inhibiting biological activity or creating sludge contamination problems. If passed through the sewer system into a receiving stream or river, the pesticide may have effects on aquatic organisms. The Agency has increasingly become aware of problems from indirect discharge facilities, and proposes a label statement that would require pesticide users to notify their receiving sewer system authority prior to discharging. The form and consequence of this notification would not be prescribed by a label statement, but notification would allow the municipal system to be knowledgeable about the pesticides that are received by their facilities.

*K. Flammability Statements*

Existing regulations in 40 CFR 162.10(h)(2)(iii) require the term "flammable" for any product whose flash point, as determined by testing conducted in accordance with 40 CFR Part 158, falls between 20°F and 80°F. In order to be consistent with regulations issued under the Hazardous Materials Transportation Act, and with proposed regulations under the Federal Hazardous Substances Act, the upper limit would be extended from 80°F to 100°F. Products whose flash points fall at or below 20°F (extremely flammable) and those above 100°F would not be affected by this change. A product with flash point between 80°F and 100°F would, under this proposal, bear labeling of greater stringency than before. Tables 1 and 2 of § 156.58 reflect this change.

At the same time, EPA is proposing to permit a declaration of non-flammability on labels under specified circumstances. Claims for non-flammability have in the past been considered implied safety claims and therefore misleading statements. In some use situations, the knowledge that a product is nonflammable is not only beneficial but essential in the use and handling of the product. Examples of such use situations are in and around electrical machinery, around power lines and in hospital operating rooms. Provided that the factual statement is not applied to products that have no reasonable expectation of flammability under any circumstances, such as water-based products, and provided that the statement is not emphasized in a manner that implies safety, a product meeting the standards set out in this section could be labeled as "non-flammable." The Agency would reserve the right to determine whether the claim is reasonable, after review of the composition and uses of the product, and the data submitted to support the claim.

*L. Classification Statements*

Section 3(d) of FIFRA requires that each pesticide product be classified for restricted use or general use. The 1975 regulations require that a statement of classification appear on the label. The Agency now believes that the phrase "general use" is potentially misleading if a user infers from the statement that the product may be used for "general" purposes not listed on the label. The Agency believes that the intent of the statute to distinguish between products whose uses are restricted and those products whose uses are not restricted can be effected by labeling of those that are restricted. Section 156.62 proposes that products classified for restricted use bear a statement to that effect; products classified for general use would not be permitted to bear a statement of classification. The few products that may have been classified by the Agency for general use would be granted ample time to make the change, and use up old stocks of labels bearing the general use classification statement.

Further, the Agency proposes to modify the restricted use statement, by changing the text to read, "For retail sale to and use only by a Certified Application for uses authorized by his certification, or by persons under his direct supervision."

In the context of restriction of pesticide use, the Agency is considering establishing, probably under the authority of section 3(d)(1)(C)(ii), a series of defined user categories, such as pest control operator, arborist, and the like, that could be used by either the Agency or the registrant to restrict the use of a product when desired or deemed necessary. Unlike the certified applicator program currently in use under FIFRA sec. 3(d)(1)(C)(i), the use of these categories on labels would not necessarily result from any toxicity considerations, but might encompass considerations such as product performance, specialized equipment needs, or particular expertise.

Designations of this nature have been used on labels, both with and without Agency sanction, for a number of years. Before the inception of the certified applicator program, the Agency itself imposed such restrictions on products having toxicity characteristics that made their availability to the general public unacceptable. Since 1975, the Agency has generally used the certified applicator program when it wished to restrict a product's use, because of its clear authority to regulate and enforce certified applicator restrictions. However, the Agency has continued to accept voluntary registrant restrictions, adhering to the logic that the registrant must have good reason for desiring to limit the sale and distribution of his product, and recognizing that such restrictions also reduce exposure potential and environmental effects. The problem that arises with such voluntary restrictions is that the States, who have primary authority for enforcement of misuse under FIFRA sec. 12(a)(2)(G), cannot always discern from the label statements who the intended users of the product are. The States have also

relied heavily on the certified applicator program, and have defined categories of certified applicator, but have not generally defined categories of users who are not certified applicators. Designation of additional categories of users could be used to bridge the gap between products which are available for use by anyone, and those that must be restricted because of toxicity considerations to certified applicators.

The Agency will be working with the States through the State FIFRA Issues Research and Evaluation Group (SFIREG) to develop candidate user categories that could be adopted by the Agency and the States. Meanwhile, the Agency would like comment on this subject, particularly as to potential user categories, and criteria for defining such user categories.

*M. Reentry Restrictions*

The 1975 regulations in § 162.10(i)(2)(viii) specify that each pesticide product must bear a reentry interval statement that meets the requirements of 40 CFR Part 170, Worker Protection Standards for Agricultural Pesticides, which provides standards for farm worker protection and notification. Briefly, Part 170: (1) Prohibits application of pesticides when unprotected persons are in the treatment area; (2) prohibits an owner or lessee from permitting reentry into treated fields by unprotected workers until exposure to the pesticides has been generally reduced by drying of sprays or settling of dusts; (3) establishes minimal time intervals for 12 specific chemicals, during which no reeentry is permitted without protective clothing; (4) provides that more stringent reentry restrictions may be established by States; (5) provides that more stringent reentry requirements contained on an individual pesticide label shall take precedence; and (6) requires oral or written warning to workers. EPA has developed data requirements upon which to base accurate and realistic reentry interval statements. Subdivision K of the Registration Guidelines addresses the factors involved in assessing exposure to workers after application of a pesticide, the types of data needed to make the assessment, and approaches for estimating appropriate reentry intervals based on data.

EPA is proposing in this part to continue in effect the 1975 labeling requirements based on Part 170. Because, however, the 1975 regulations did not specify the form or wording of label statements that met the requirements of Part 170, it has been difficult for registrants to comply with the 1975 regulations. Section 156.67 proposes statements for all products intended for outdoor agricultural use using hand labor.

The statements being proposed are consistent with those required by PR Notice 83-2, issued March 29, 1983. Products would have to be labeled with statements concerning exposure of persons in treated areas, reentry intervals if established by Part 170 or the Agency, warnings to workers, and, if products are in Toxicity Category I or II, certain statements in Spanish for the benefit of field workers who are not literate in English. The Agency would like comment on whether Spanish language requirements should be expanded to include products in Toxicity Categories III and IV.

EPA believes that oral warnings or posting of agricultural fields and outdoor areas, and placarding of structures and vehicles, are a necessary adjunct to labeling to ensure that persons who do not have access to the label information are at least made aware of the application of and potential exposure to the pesticide. Section 156.67(a)(7) would provide that the label require oral or written warnings or posting and would prescribe the content of any posting statement.

Part 170 is targeted specifically to "farm workers performing hand labor operations in fields after ground * * *, aerial, or other types of application of pesticides." However, EPA does not believe that reentry hazards should be perceived only as an agriculturally oriented problem. Adequate protection should be offered to all workers regardless of use situation. Fumigation in enclosed spaces, in particular, has the potential for serious harm if entry is gained into the treatment area without proper precautions. Accordingly, 40 CFR Part 158 requires exposure data for certain indoor fumigant uses, and § 156.67 correspondingly would require label statements pertaining to entry into fumigated areas such as structures and vehicles.

EPA is currently reevaluating its Part 170 rules, and intends to propose new standards for farmworker protection in the future. To the extent that the new standards would require modifications to the labeling requirements of § 156.67, EPA would revise this rule.

Reentry restrictions provided by Part 170 are not appropriate to indoor fumigant applications. Therefore, the label statements contemplated by Part 170 would not be required by this section. Other more appropriate statements are included in § 156.67(b).

*N. Disposal Statements*

In 40 CFR Part 165, Subpart C, Recommended Procedures for the Disposal and Storage of Pesticides and Pesticide Containers, issued in 1975, EPA described recommended storage and disposal practices for pesticides and their containers. Since 1975, EPA has required on labels a series of disposal statements consistent with the prohibitions and recommended practices of that subpart. Data requirements to enable the Agency to define acceptable disposal methods for individual pesticides will in the future be proposed for inclusion in Part 158.

Since the issuance of Part 165 recommended procedures, the Resource Conservation and Recovery Act (RCRA) has been enacted, and a series of implementing regulations promulgated under its authority. Pesticide and container disposal may be regulated under both FIFRA and RCRA. The 1975 regulations require that acceptable disposal practices be stipulated on the pesticide label. A user who fails to follow label disposal instructions has misused the pesticide in violation of FIFRA sec. 12(a)(2)(G).

The labeling requirements proposed in this section are designed to be as consistent with RCRA as is possible under the FIFRA regulatory scheme. Because FIFRA requires that the Agency make determinations of health and safety on an individual product basis, EPA proposes to apply certain of the hazardous waste criteria based on pesticide formulation characteristics rather than generic or sole active ingredient characteristics used under RCRA rules. (The reference to "active ingredient" in RCRA regulations does not conform to that under FIFRA. "Active ingredient" under FIFRA refers to a pesticidally active ingredient, whereas under RCRA, "sole active ingredient" refers simply to the principal component of the product—as if the product were generically composed only of that ingredient.)

Briefly, the Agency would apply the toxicity criteria of 40 CFR 261.11(a)(2) for listing acutely hazardous ingredients on the RCRA "E" list to pesticide formulations as proposed for registration. Similarly, the Agency would apply the criteria in 40 CFR 261.21 through 261.23 for flammability, corrosivity, and reactivity to pesticide formulations as proposed for registration. On the other hand, EPA would use the "F" list (40 CFR 261.33(f)) generically as the basis for labeling a pesticide formulation as a toxic waste. A product would be labeled as a toxic

waste if it contained any of the ingredients on the F list in any concentration. Similarly, the Agency would consider the 14 chemicals listed in 40 CFR 261.24 because of extraction procedure (EP) toxicity (a test for potential leachability under landfill conditions) on a generic basis.

The Agency believes that a product-specific approach is not only feasible but preferable under FIFRA. The Act requires that the Agency evaluate and register pesticide formulations, most of which are mixtures of ingredients that currently are regulated under RCRA only as generic or sole active ingredients. In order to evaluate the product for registration, the Agency requires the submission of considerable data on the toxicological and physical characteristics of the pesticide formulation, and on each separate active ingredient in the formulation (or the technical product from which it is derived), but not generally for ingredients that are pesticidally inert. With specific formulation data in hand, the Agency is in a position to judge a pesticide formulation as a whole against hazardous waste criteria. Thus in many cases an accurate determination can be made that the product as distributed and sold commercially (a "commercial chemical product" in RCRA parlance) would or would not be a hazardous waste if disposed of.

First, the Agency proposes that products that meet the listing criteria of § 261.11(a)(2) be labeled as "acutely hazardous wastes." Under RCRA, the criteria of that section are used as the basis for the "E" list of commercial products that are acutely hazardous if they contain the listed ingredient as a sole active ingredient. A pesticide formulation that contains a relatively small amount of a single E-listed ingredient (a "sole active ingredient"), and yet as a formulation does not meet the acute toxicity criteria, could nonetheless, under RCRA regulations, be considered an "acute hazardous waste," subject to all the disposal requirements applied to acute hazardous wastes. The Agency believes that a strict interpretation of the RCRA E list, without consideration of the concertation limits of the listed hazardous ingredient in a diluted formulation mixture, results in inaccurate characterization of many commercial pesticide products as acute hazardous wastes. The consequence is that unwarranted disposal burdens are imposed on pesticide users.

On the other hand, EPA believes that there may be pesticide formulations that would meet the acute toxicity listing criteria, but which, because the active ingredients are either not E-listed or are present in mixtures that do not meet the definition of "sole active ingredient," are not regulated under RCRA. This could create potential risks by disposal in a non-approved manner. This proposal would remedy this situation, since all pesticide products would be evaluated against the acute toxicity criteria, regardless of whether they contained an E-listed ingredient or were a component of a mixture. In summary, EPA believes that designation of pesticides as acute hazardous wastes will be more accurately, consistently, and comprehensively administered if toxicity criteria are directed at all pesticides formulations as proposed for registration and not just at the formulations containing E-listed ingredients as sole active ingredients.

The Office of Solid Waste and Emergency Response is developing a proposal that would address mixtures as acute hazardous wastes under RCRA. (Mixtures are not currently regulated as hazardous wastes under RCRA.) Because acute toxicity data on mixtures are rarely available (pesticide mixtures are the exception), the proposal would base the E-list determination upon $LD_{50}$ values extrapolated from those of the components of the mixture.

Second, under RCRA, hazards other than acute toxicity are addressed by applying a number of factors specified in 40 CFR 261.11(a)(3) to a group of chemicals known or believed to pose hazards. (Appendix VIII of 40 CFR Part 161). Those chemicals which are distributed and sold as commercial products are placed on the RCRA "F" list (40 CFR 261.33(f)). The Agency believes that when addressing chronic effects where quantitative hazard limits are either not feasible or not scientifically tenable, the Agency should evaluate products on a generic basis. In some cases, such as carcinogenicity, the Agency's position is that there is no lower concentration limit below which an ingredient does not pose the hazard. Thus any amount of a carcinogen in a product would be sufficient to warrant designation as a toxic waste. This proposal would designate any product that contains an F-listed chemical in any amount as a "toxic waste" on the basis of that ingredient.

Finally, any product (not limited to generic or single active ingredients) may be a hazardous waste under RCRA if it meets certain physical/chemical hazard characteristics defined in Subpart C of 40 CFR Part 261 (flammability, corrosivity, reactivity and Extraction Procedures (EP) toxicity). Pesticide regulations in 40 CFR Part 158 require the submission of data on product flammability, corrosivity, and, if applicable, reactivity. These criteria would be applied to the pesticide formulation as the basis for a "hazardous waste" labeling statement.

Data are not required by Part 158 for the EP toxicity test in 40 CFR 261.24 (although a test for leaching potential is required), so the Agency cannot evaluate individual pesticide formulations at the time of registration to determine whether they meet the EP toxicity test. Nor would the EP toxicity test be applicable to a pesticide formulation, since it was intended to identify toxic constituents (i.e., single active ingredients) of concern. EPA would, therefore, adopt the same generic approach as it would for F-listed chemicals, except that products containing the § 261.24 ingredient would be identified on the label as "hazardous wastes."

Products would be identified on the label as "acutely hazardous," "toxic," or "hazardous" wastes, in that order of precedence. Thus, a product that meets the criteria for more than one labeling designation would be labeled with the designation of highest concern. A product that, as a formulation, met the criteria for "acute hazardous" identification, would be labeled as such, regardless of the presence of any F-listed or § 261.24 ingredient. A product containing a pesticide that was both F-listed and in § 261.24. (as is the case with three pesticides) would be labeled as a "toxic waste" rather than a "hazardous waste." Products containing pesticides which met neither the criteria for "acutely hazardous" designation nor that for "toxic" designation, would be designated as "hazardous" wastes if they met the flammability, corrosivity, or reactivity criteria (as a formulation) or contained any amount of a § 261.24 ingredient. Although this last would categorize some products as hazardous wastes that might not meet the EP toxicity test criteria, applicants would be free to conduct the EP toxicity test to demonstrate that fact, which could serve as the basis for modification of the disposal statement.

In summary, § 156.70(c) lists criteria which, if met, would cause a pesticide product to bear statements alerting the user to the hazardous nature of any wastes, and requiring disposal in accordance with State or Federal requirements for such products. The criteria are:

1. The product is in certain Toxicity Categories defined in § 156.42. This criterion incorporates the listing criteria

for the E list of acutely hazardous wastes of § 261.11(a)(2), including acute oral and dermal toxicity corresponding to Toxicity Category I, and acute inhalation toxicity criteria corresponding to Toxicity Categories I and II. In addition, § 261.11(a)(2) states that if a product is "* * * capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness," it may be listed on the E list. The Agency believes that pesticides that are corrosive to eye or skin or cause severe eye irritation for more than 21 days (Toxicity Category I) clearly meet this latter criterion, and has proposed to include such products in this section.

2. The product contains any substance listed in 40 CFR 261.33(f) (the F list). The F list contains substances that are considered hazardous, but do not meet the acute toxicity criteria of the E-list. Hazards addressed on the F-list include lesser acute hazards, chronic hazards such as carcinogenicity, mutagenicity and teratogenicity, and physical/chemical hazards such as ignitability, reactivity or corrosivity.

3. The product exhibits the characteristic of flammability, corrosivity, reactivity, or contains a pesticide listed in 40 CFR 261.24. These characteristics are indicators of physically or chemically hazardous properties that would render a product a hazardous waste.

The disposal statements prescribed by Table 1 of § 156.70 would not instruct the user exactly how to dispose of his waste pesticide product, other than by legal use in accordance with the label instructions. Legal disposal of a hazardous waste under RCRA depends not only on product composition and characteristics, but also on user identity and quantity of pesticide waste generated. Label statements that address these factors for a single product cannot be easily devised. The label statements, therefore, refer the user to his EPA Regional Office or State Environmental Control Agency for information on proper and legal disposal.

Distinguishing between hazardous waste and non-hazardous waste is necessary only for pesticide disposal. For pesticide containers, which may also be classified as hazardous wastes under RCRA, the label statements in Table 2 of § 156.70 would obviate the need for RCRA hazardous waste disposal procedures. If label statements for container disposal are followed, the container could be disposed of by normal procedures under Subtitle D of RCRA (at the use site or in regular solid waste facilities such as landfills, for example).

The Agency recognizes that a single set of statements, regardless of flexibility, cannot address the multiplicity of containers and pesticide types currently registered. Moreover, disposal practices are often further regulated at the State or local level. Section 156.70(e) therefore would permit registrants to propose alternative statements, consistent with RCRA, that express the available disposal options with greater definition. Moreover, as the Agency receives and evaluates data leading to specific disposal methods for pesticides, the labels of such products would be required to be modified to provide more exact information on acceptable methods of disposal.

*O. Specific Use Directions and Restrictions*

Section 156.72 would establish the types of information required in the use directions of any product. Section 156.76 would set out use restrictions that might be imposed. Neither is intended to describe detailed requirements applicable to specific types of products. Guidance on use directions specific to product type may be found in Subdivisions 101 through 106 of the Registration Guidelines. The only exception is that antimicrobial products of public health significance would be required to be labeled according to efficacy performance standards in Subpart P of this Part.

For the most part, §§ 156.72 and 156.76 proposed labeling requirements that incorporate requirements imposed in the past only on a case-by-case basis. However, several points in this section are noteworthy:

1. Labels would be required to express clearly the sites of use intended by the registrant. Specific data requirements for exposure to various segments of the user and non-target populations are still in development. In the absence of exposure data, EPA may need to use the label descriptions of the intended sites of use to identify and assess the possible exposure paterns to be expected.

2. Products intended for aerial, mist blower, or ground hydraulic application would, when data demonstrate significant determental effects, be required to bear instructions on methods of reducing pesticide spray drifts. This requirement necessarily would be imposed on a case-by-case basis, dependent upon the toxicity of the product to man and non-target species, its phytotoxicity, its proposed use patterns, and application technique.

The Agency would like comment on the possibility of requiring "downstream" labeling of consumer products treated with pesticides. The Agency believes that treated substances or articles have repeated or regular human contact should bear statements of the potential hazard of the product. The Agency could accomplish this under FIFRA by requiring that a pesticide product designed to be incorporated in a substance or article must be labeled with a statement requiring the subsequent user (the manufacturer of the treated material) to label the consumer product with a statement that the material had been treated with the pesticide. The downstream manufacturer would be in violation of the misuse provisions of FIFRA if he failed to label the materials as specified on the labeling. EPA contemplates that this requirement might be imposed for products intended for incorporation into materials such as fabrics and textile goods intended for human clothing (diapers and socks for example), wood articles having substantial human contact (toilet seats), indoor paints, mattresses and rugs. EPA notes that OSHA regulations require downstream labeling of chemicals used in the workplace, and views the labeling of pesticide-treated consumer materials as an analogous regulatory situation. Comments are welcomed, together with suggestions as to how best to delineate, both in regulation and on the label, the universe of consumer products for which labeling statements would be appropriate.

*P. Labeling of Products Not Required to be Registered*

FIFRA authorizes the Agency to regulate the labeling of all pesticides and pesticidal devices. The misbranding provisions of FIFRA sec. 2(q) do not distinguish a registered product from an unregistered product in applying the misbranding criteria.

The Agency has not chosen previously to promulgate specific regulations interpreting the misbranding provisions of FIFRA as they apply to unregistered pesticides. Subpart F would describe affirmative requirements that will ensure that products not required to be registered nonetheless maintain labeling standards comparable to those for registered products. The Agency believes that setting out affirmative requirements would be beneficial for producers of such products, who would then be able to ascertain whether they were in compliance with the misbranding provisions of the Act.

The affirmative requirements of these sections are derived from §§ 162.5 and 162.15 of the 1975 regulations, which delineated the misbranding provisions of FIFRA applicable to non-registered products of various types, and from previous Agency interpretations and policy statements.

*Q. Efficacy Performance Standards*

Subpart P (§§ 156.300 through 156.380), Labeling of Antimicrobial Products, proposes labeling requirements for certain antimicrobial products. The efficacy performance standards upon which the proposed statements are based are derived from the testing requirements of proposed 40 CFR Part 158. Antimicrobial products are identified on the label as sterilizers, disinfectants, sanitizers, or bacteriostats, depending on their level of antimicrobial activity. A product that does not meet the performance standard of Subpart P for a particular level of activity (sterilizer, disinfectant, or sanitizer) could not be identified as such on the label. This would not preclude its being labeled for any lesser degree of activity if it met the performance standard for that lesser activity level.

Section 156.305(b), Limited efficacy claims, has been changed to reflect new policy. In the past the products which were considered within this section were usually effective against a group of organisms such as gram negative organisms. The Agency has concluded that a claim based on killing gram negative organisms only is meaningless to the user since he is not able to determine what spectrum of organisms are in fact present on objects to be disinfected. The Agency therefore proposes to allow such limited claims only if the user clearly can discern from the label the organism he wants to control and the label can provide directions on where and how to control that particular pathogenic organism without being misleading.

**III. Implementation**

After promulgation, this revised rule would be implemented for existing products primarily through the reregistration program mandated by FIFRA sec. 3(g). EPA would apply the rules to products as they are required to be reregistered over a period of several years. This gradual implementation will allow ample time for registrants (including those whose products are registered by States under FIFRA sec. 24(c)) to make required label revisions without unduly burdening individual registrants, or disrupting the supply of pesticides.

Additionally, the Agency may selectively implement certain provisions of this rule through its Label Improvement Program. This program, instituted on June 5, 1980 (45 FR 37884), is a mechanism by which the Agency can focus its labeling efforts on potentially hazardous or unenforceable label deficiencies affecting a group of common products.

Finally, the rule would be applicable to new products registered after the effective date.

**IV. Executive Order 12291**

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. The Agency has conducted a Regulatory Impact Analysis and has determined that this proposal is not a major regulation. This proposal does not require additional persons to label pesticide products. Pesticide products are required to be labeled by the Act itself. Part 156 describes the content and format of the label necessary to comply with the Act and to allow persons to use pesticides and pesticide devices safely. Based on current costs for printing of new labels of $500 to $1,000 per product, the cost for relabeling the approximately 40,000 registered products would be $20 million to $40 million. Since only about one-eighth of the products are amended or reregistered each year, the annual cost would be between $2.5 million and $5 million.

The underlying data supporting labeling statements are submitted to satisfy the requirements of proposed Part 158, for which a comprehensive Regulatory Impact Analysis has been prepared. Compliance with this proposed regulation:

1. Would not result in an annual effect on the economy of $100 million or more.
2. Would not result in significant increases in costs to individual companies or users.
3. Would not have a significant impact on a substantial number of small entities.
4. Would result in benefits to pesticide users through consistency and completeness of pesticide labeling information.

This proposal was submitted to the Office of Management and Budget for review, as required by Executive Order 12291.

**V. Regulatory Flexibility Act**

Pursuant to section 3 of the Regulatory Flexibility Act, each proposed regulation is to be accompanied by a Regulatory Flexibility Analysis or by a certification that no such analysis is necessary because the regulation, if promulgated, will not have significant economic impact on a substantial number of small entities. The Agency has conducted a preliminary analysis, and has determined that a Regulatory Flexibility Analysis is not required. That analysis concluded that for small businesses (fewer than 500 employees), the cost of compliance with this proposal would be 0.5% of estimated sales per product. This percentage is not considered significant. For this reason, I hereby certify that the proposed Part 156 regulations on Labeling Requirements for Pesticides and Devices do not have a significant impact of a substantial number of small entities.

**VI. Paperwork Reduction Act**

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and has assigned OMB Control Number 2000–0483. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB, marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

**VII. Statutory Review**

In accordance with FIFRA section 25, this proposal was submitted to the U.S. Department of Agriculture for comment. USDA comments and EPA responses to those comments are addressed below.

1. USDA stated its opinion that the proposal underestimates the costs of complying with the labeling provisions, asserting that that the primary costs of relabeling lie not in the printing of labels but in the design and execution of the label. The Regulatory Impact Analysis conducted for this proposal addressed these costs, and, based on discussions with industry personnel, the Agency estimates the cost of developing new printing plates ranges from $1,000 to $2,000 per product. For all 40,000 registered products this amounts to a one-time cost of $40 to $80 million to the industry. Since, however, the revisions will be accomplished over a period estimated at 8 years, the annualized cost will be between $5 and $10 million. This is viewed as an upper bound, since there will be a certain number of registrants who seek amended registration regardless of the new requirements, and thus would revise their labels for rasons unrelated to this proposal.

2. USDA also commented that, although it agrees with the Agency's goal of prescribing labeling that will encourge users to read the label, and will promote understanding, the length and detail of the label information may have the opposite effect. EPA acknowledges that the amount of information on labels is extensive and that its length and complexity have increased over the years. The phenomenon, however, can only partly be attributed to the Agency's labeling regulations.

The labeling reqirements in this proposal are derived from the misbranding provisions of the Act that require that labeling be "adequate to protect health and the environment." This broad general mandate means that labeling requirements must be compehensive. Moreover, the label, under FIFRA, serves both as an information vehicle and as the standard for enforcement of many of the Act's provisions. The enforcement aspect of labeling tends to increase the amount and complexity of detail needed on labels.

On the other hand, the industry often has reason to include additional label informtion, quite apart from the requirements of the statute and Agency regulations. Marketing considerations and potential liability are factors contributing to increased label complexity that are not of direct concern to EPA. The desire to expand the uses for which a product is registered means that an individual product, particularly one for agricultural use, may be registered for dozens of uses, each with directions and restrictions on use. Expanding usage of a single product is often more desirable from a marketing perspective (and usually easier to accomplish) than registering a number of similar products, each with fewer uses. For liability reasons, companies often voluntarily provide additional information on the label, particularly in the area of precautionary statements.

Taken together, these various factors do result in labeling of greater length, detail and complexity than is desirable from a user point of view. EPA shares USDA's concerns in this area. EPA is exploring ways in which label information may be provided more efficiently and effectively from a user standpoint, and welcomes suggestions and comments on possible ways of accomplishing this goal.

Copies of this proposal were supplied to the Committee on Agriculture of the U.S. House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the U.S. Senate. Neither Committee commented on the proposal.

Copies of this proposal were submitted to the FIFRA Scientific Advisory Panel (SAP) for review. The SAP, in reviewing the proposed revisions to the Toxicity Categories (§ 156.42), waned to know where and how chronic toxicity is considered in categorizing pesticides into groups.

The toxicity categorizations in § 156.42 are based on acute toxicity criteria only; they ae not intended to encompass subchronic and chronic toxicity. The toxicity categories are a convenient reference point for regulating pesticides when acute hazards are of concern. EPA may also impose special labeling pertaining to subchronic or chronic hazards on an individual chemical basis. This has been done primarily when the Agency has identified a potential risk for a chemical based on subchronic or chronic hazard, conducted a risk/benefit analysis, and concluded that the risks of one or more uses are outweighted by the benefits of those uses. In this case, the product registrations for that use have been continued, but often with the requirement that the label bear statements of the nature of the hazard.

**List of Subjects in 40 CFR Part 156 and Part 167**

Environmental protection, Labeling, Pesticides, Recordkeeping and reporting requirements.

Dated: September 18, 1984.

**William D. Ruckelshaus,**

*Administrator.*

Therefore, it is proposed that 40 CFR be amended as follows:

1. By adding Part 156, to read as follows:

## PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

### Subpart A—General Provisions

Sec.
156.1 Purpose, scope and applicability.
156.3 Definitions.
156.5 Requirement for labeling.
156.7 Placement of label.
156.10 Format of label.
156.15 False and misleading statements.

### Subpart B—Product Identification

156.20 Product name.
156.22 Pesticide type.
156.25 Identification of registrant.
156.27 Optional identification elements.
156.30 Product registration number.
156.31 Producing establishment number.
156.34 Ingredients statement.
156.36 Net weight or measure of contents.

### Subpart C—Warnings and Precautionary Statements

156.40 Content and format.
156.42 Toxicity category.
156.44 Signal word.
Sec.
156.46 Child hazard warning.
156.48 Statement of practical treatment.
156.49 Note to physician.
156.50 Inert ingredient labeling.
156.52 Human hazard precautionary statements.
156.55 Environmental hazard statements.
156.58 Physical/chemical hazard statements.

### Subpart D—Use Directions and Restrictions

156.60 General.
156.62 Classification statement.
156.64 Misuse statement.
156.67 Worker protection statements.
156.70 Storage and disposal statements.
156.72 Directions for use.
156.76 Restrictions on use.

### Subpart E—Specialized Labeling

156.80 Manufacturing use products.
156.87 Unit packaging.

### Subpart F—Labeling of Products Not Required to be Registered

156.105 Products shipped between registered establishments.
156.110 Products for export only.
156.112 Products shipped under an emergency exemption.
156.115 Products shipped for disposal only.
156.118 Pest control devices.

### Subparts G Through O—[Reserved]

### Subpart P—Labeling Requirements for Certain Antimicrobial Products

156.300 Sterilizers for use on hard surfaces.
156.305 Disinfectants for use on hard surfaces.
156.310 Fungicides for use against human pathogenic fungi.
156.315 Virucides.
156.320 Tuberculocides.
156.325 Phenol coefficient.
156.330 Products for use against other microorganisms.
156.335 Sanitizers for hard non-food contact surfaces.
156.340 Sanitizers for hard food contact surfaces.
156.345 Products providing residual activity for use on hard surfaces.
156.350 Laundry additives.
156.355 Fabric and textile products.
156.360 Air sanitizers.
156.365 Toilet bowl and urinal treatments.
156.370 Human drinking water treatments.
156.375 Swimming pool water treatments.
156.380 Health-related and non-health-related claims for antimicrobial products.

**Authority:** Secs. 2, 3, 5, 6, 7, 9, 10, 12, 17, 19, and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136–136y

### Subpart A—General Provisions

#### § 156.1 Purpose, scope, and applicability.

(a) *Purpose.* The purpose of Part 156 is to describe the content of the label and labeling for pesticide products that is necessary to comply with statutory requirements and that, if adhered to by

users, will protect public health and the environment from unreasonable adverse effects.

(b) *Scope.* This part specifies acceptable physical characteristics of the label and labeling, including requirements pertaining to placement, size, color, and typography. Further, this part describes the content of labeling, including product identification, hazard warning statements, use directions, and restrictions on use.

(c) *Applicability.* (1) The requirements of this part apply to all pesticide products and devices.

(2) At the time of an application for registration or amended registration, an applicant or registrant may present evidence to demonstrate that a particular requirement or labeling statement prescribed by this part is inappropriate for his product because of special circumstances of composition, use or packaging. Based on such evidence, the Agency may waive or modify a requirement, or may permit alternative labeling statements to be used.

(d) *Use of terms.* Mandatory specifications are indicated by the use of the terms "must", "shall", "may not", and ". . . is not acceptable". Where requirements are not imposed, Agency-preferred, recommended or optional labeling is indicated by the terms "may" and "should".

(e) *Enforcement*—(1) *Misbranding.* Except as specified by FIFRA sec. 12(b), it is unlawful under FIFRA sec. 12(a)(1)(E) and (F) to distribute, ship, or sell a misbranded pesticide product or device. Misbranding is also a basis for denial or cancellation of registration of a pesticide product. A misbranded pesticide or device is one bearing labeling that does not conform to the requirements of FIFRA sec. 2(q). Any pesticide product or device that does not comply with the requirements of this part is considered by EPA to be misbranded within the meaning of FIFRA sec. 2(q). Information not required by this part on a product label does not necessarily constitute misbranding; however, if such information is misleading or violates other specific requirements, the product may be deemed misbranded.

(2) *Misuse.* FIFRA sec. 12(a)(2)(G) provides that it is unlawful to use a registered pesticide in a manner inconsistent with its labeling. This applies not only to labeling statements and information required by this Part, but also to precautions, directions, and restrictions that are voluntarily included on labeling by the registrant. The user who fails to follow any label instructions may be held to be in violation of the misuse provisions of the Act.

**§ 156.3 Definitions.**

Words and terms used in this part have the meanings set forth in the Act and in 40 CFR 152.2. In addition, the following terms are defined for the purposes of this part:

(a) "Bulk container" means any mobile or stationary container used for transporting or storing pesticides in quantities greater than 55 gallons liquid or 100 pounds solid or semi-solid. The term includes, but is not limited to, tank trucks, cargo vessels, railroad tank cars, rail freight cars, storage tanks, and "nurse tanks." The term excludes containers used in the application of pesticides after dilution by the user.

(b) "Front panel" means the larger of the following:

(1) That portion of the area of a pesticide container that is ordinarily visible to the purchaser under the usual conditions of display for sale; or

(2) An area not less than 25 percent of the surface excluding the shoulder, neck and handle if these are part of the container.

(c) "Immediate container" means that container which is directly in contact with the pesticide or device.

(d) "Label" means the written, printed or graphic matter on or securely attached to the outer or immediate container of the pesticide or to the device.

(e) "Labeling" means the label and any technical bulletin, material safety data sheet, brochure, circular, leaflet, pamphlet, insert, printed advertising or any other printed or graphic matter to which reference is made on the label, or which accompanies the product at any time in distribution or sale. Advertising material not accompanying the product is not considered labeling.

(f) "Outer container" means a container or wrapper that is not in direct contact with the pesticide product, in which single or multiple immediate containers or unit packages are distributed.

(g) "Securely attached," when used with respect to a label, mean that:

(1) The label is not detachable from the immediate or outer container without destruction or defacement of the printed or graphic matter contained thereon; or

(2) The label can reasonably be expected to remain affixed to the immediate or outer container during the time that the product is held for distribution, sale, and use, under the conditions likely to be encountered during that time.

(h) "Trademark" means any word, letter, or symbol used in connection with a pesticide product or device which distinctly identifies the origin or ownership of the article or substance to which it applies.

(i) "Use" means any activity covered by the pesticide label including, but not limited to, application of a pesticide, mixing and loading, storage of pesticides and pesticide containers, disposal of pesticides and pesticide containers, and reentry into treated areas.

**§ 156.5 Requirements for labeling.**

(a) *Registered pesticide products.* Each pesticide product registered under FIFRA sec. 3 or 24(c) shall bear a label or labeling, the contents and form of which shall conform to the requirements of this part.

(1) An end use product shall be labeled in accordance with this part, as applicable. The instructions provided in the latest edition of Subdivision H of the Registration Guidelines are acceptable to comply with §§ 156.72 and 156.76.

(2) A manufacturing use product shall be labeled in accordance with § 156.80.

(3) A unit package shall be labeled in accordance with § 156.87.

(b) *Devices and non-registered pesticide products.* Each unregistered pesticide product or device that may be legally distributed or sold, or transferred without prior registration (see § 152.30) shall bear labeling, the contents and form of which shall conform to the requirements of this part as specified below:

(1) If the product is to be transferred between two registered establishments operated by the same producer, or for further processing, packaging or labeling, in accordance with § 152.30(a) or (b), the labeling shall meet the requirements of § 156.105.

(2) If the product is to be distributed or sold in accordance with the terms of an experimental use permit under 40 CFR Part 172, the labeling shall meet the requirements of that part.

(3) If the product is to be transferred solely for export to another country, the labeling shall meet the requirements of § 156.110.

(4) If the product is to be transferred in accordance with an emergency exemption, the labeling shall meet the requirements of § 156.112.

(5) If the product is to be transferred solely for purposes of disposal, the labeling shall meet the requirements of § 156.115.

(6) If the product is a device, as defined by FIFRA sec. 2(h), the labeling shall meet the requirements of § 156.118.

(7) If the product has been exempted from registration under FIFRA sec. 3 by a regulation issued under FIFRA sec. 25(b) that requires that the product be labeled, the labeling shall meet the requirements established by that regulation.

(c) *Failure to label correctly.* (1) If the pesticide product or device does not bear a label, the product is misbranded under FIFRA secs. 2(q)(2)(C), and 12(a)(1) (E) and (F).

(2) If the pesticide product or device bears labeling that fails to conform to the requirements of this part, the product is misbranded under FIFRA sec. 2(q)(1)(E), and may be misbranded under other provisions of FIFRA sec. 2(q).

**§ 156.7 Placement of lable.**

(a) *Immediate container.* Except as provided by paragraphs (c) and (d) of this section, the label must be displayed on or be securely attached to the immediate container of the pesticide product.

(b) *Outer container.* If the immediate container is enclosed in a wrapper or outer container through which the label cannot be clearly read at the time of retail sale, the label must also be displayed on or be securely attached to such wrapper or outside container.

(c) *Bulk container*—(1) *In transit.* A pesticide in transit in a bulk container must meet the requirements of 49 CFR Part 170 through 189, with respect to placement and content of labeling. In addition, a copy of the pesticide labeling must either be attached to the papers that accompany the shipment and left with the consignee at the time of delivery, or be attached to the immediate bulk container.

(2) *In storage.* A pesticide product stored in a bulk container that remains in the custody of the user, must have a copy of the labeling securely attached in the immediate vicinity of the discharge control value.

(3) *Distribution from bulk container.* If a pesticide product is distributed directly from a bulk container to a container provided by an individual user, the distributor must securely attach a copy of the labeling to that container.

(d) *Unit package.* A product distributed in unit packages shall bear a label on both the unit package and the outer container.

**§ 156.10 Format of labeling.**

(a) *Placement and prominence of labeling elements.* (1) Any word, statement, design or graphic representation required to appear on the labeling, either by this part or on a case-by-case basis for individual products, shall be located as prescribed in this part, unless the Agency states otherwise. Designation of location may be specific, such as "on the front panel," or may be in relation to other labeling statements and designs, such as "in the use directions".

(2) If no specific location is designated, or if the inclusion of the information is optional on the part of the registrant, the information may be placed in any reasonable location on the labeling. An optional statement or design shall not be placed so as to crowd, obscure, or obliterate required information, nor may it detract from required information by size, color, configuration, or prominence.

(3) All words, statements, graphic representations, and designs required by the Act and this part must be clearly legible to a person with normal vision. They shall be displayed with such conspicuousness that they would likely to encourage the ordinary individual to read the labeling under customary conditions of purchase and use. Unless approved by the Agency, statements shall run parallel to the bottom of the container as normally displayed for purchase. Statements shall not be placed along seams of cans or folds of bags.

(b) *Contrast.* (1) All required text must appear on a solid background of a contrasting color. The Agency encourages the use of dark colored text (black, or dark primary colors) against a light background (white, yellow, grey, beige) for maximum contrast; however, light text on a darker background is acceptable. Labeling shall not be imprinted on highly reflective surfaces, such as Mylar or aluminum foil.

(2) All required text of labeling that is lithographed onto a glass bottle or embossed onto a plastic container must be in a color which clearly contrasts with the color of the container. If the container is transparent, the text must contrast with the contents of the container. For example, a clear glass bottle containing a brown liquid shall be labeled in a color that contrasts with brown.

(3) The labeling of a product required to bear the word POISON in red shall not have the majority of its text in red. This paragraph is not intended to preclude incedential use of red in illustrations or graphic designs, nor the skull and crossbones in red. The Agency may prescribe the use of the color red on other labeling on a case-by-case basis.

(c) *Type size and form.* (1) All required text must be at least 2 mm in size (based on the height of the upper case letters). A larger type size materially enhances the legibility of the label and is desirable. A sans-serif type face is preferred. All required headings must be distinguished from the label text by use of a color contrasting with the text, larger type size, different type face, or similar means of differentiation.

(2) Minimum type size requirements in relation to front panel size are given in Table 1 for the following labeling elements: the signal words, child hazard warning ("Keep Out of Reach of Children"), and the statement RESTRICTED USE PESTICIDE (when required).

TABLE 1—TYPE SIZE REQUIREMENTS FOR PESTICIDE LABELING

| Front panel size (Sq. cm) | Minimum type size for "Restricted Use Pesticide" (if required) and signal work in capital letters. (mm) | Minimum type size for "Keep Out of Reach of Children" (child hazard warning) (mm) |
|---|---|---|
| Up to 30 | 2.0 | 2.0 |
| Over 30 to 60 | 3.5 | 2.0 |
| Over 60 to 100 | 4.0 | 3.0 |
| Over 100 to 200 | 5.0 | 3.5 |
| Over 200 to 400 | 6.5 | 4.0 |
| Over 400 | 8.5 | 6.5 |

(3) Paragraphs should be indented, with at least two spaces between paragraphs for increased legibility. The body of the text should be printed in lower case. Capital letters, bold face type, underlining, italics, or other forms of emphasis should not be used indiscriminately throughout the labeling but should be reserved for headings or areas where particular attention by users is sought, such as use limitations or special hazards.

(d) *Language to be used.* (1) All required text must be in the English language, except as provided in paragraph (d)(3) ot this section. The Agency may require that labeling be provided in a second language.

(2) At the registrant's option, and in addition to labeling in English, the labeling may contain information in a second language. If bilingual text is used, the following statement must appear in the second language on the front panel of the label: "If you cannot read English, do not use this product until instructed on its proper use." In addition to this statement, any or all of the text may be provided in the second language. The Agency encourages registrants to provide bilingual labeling for products distributed or sold in areas where large numbers of users are not literate in English.

(3) The label of a product distributed and sold solely for use in Puerto Rico,

whose English translation has been approved by the Agency, may be solely in Spanish, provided that a statement in English similar to, "If you cannot read Spanish, do not use this product until properly instructed", appears on the front panel.

(4) Labeling in a second language must be a complete and accurate translation of the English text, and must comply with format and presentation requirements of this section.

(5) Bilingual labeling requirements for products intended solely for export are contained in § 156.110.

(e) *Use of symbols.* (1) The labeling may bear pictorial or graphic symbols in addition to text. The Agency encourages the use of symbols that enhance user comprehension, particularly in the area of hazard warnings. Because of the multiplicity of symbols currently in use, the Agency prefers the use of existing systems rather than the development of new ones.

(2) An optional symbol may be located in any position on the labeling, provided that it does not crowd, obscure, or detract from required text. A symbol may not be used in lieu of text. A symbol may be used only with accompanying explanatory text, and must be placed in close proximity to such text.

(3) Symbols required by other Federal agencies, e.g., U.S. Department of Transportation, may be used on labeling, provided they are clearly distinguished from information required by this part.

**§ 156.15 False and misleading statements.**

(a) *Warranty and warranty disclaimer statements.* A statement on pesticide labeling warranting any aspect of the product or its use, or disclaiming or limiting the operation of a warranty, shall not contain any false or misleading statements. A statement will be considered false or misleading if it contradicts, negates, or detracts from any labeling statement required by the Act or regulations, including but not limited to:

(1) In the case of a warranty statement,

(i) Stating or implying that the product may be used in any manner that would be inconsistent with the labeling within the meaning of FIFRA sec. 2(ee).

(ii) Stating that information on the labeling is provided voluntarily by the manufacturer, when in fact such information is required by the Act and regulations to appear in the labeling.

(iii) Warranting the product composition for a period of time shorter than that during which the product may be legally sold, taking into account any expiration date on the labeling.

(iv) Using the term "guaranteed" without stating what is guaranteed.

(2) In the case of a warranty disclaimer or limitation statement, disclaiming or limiting liability for damages when the product is used in accordance with the labeling direction; provided, however, that a warranty disclaimer may state limitations of liability for damages caused by circumstances, such as unforeseen post-usage weather conditions, over which neither the manufacturer nor the user has any control.

(b) *Statements relating to the composition of the product.* Statements relating to the composition of the product must be consistent with the ingredients statement appearing on the front panel. Refer to § 156.34 for further information on the ingredients statement.

(1) References in the product name to the composition of the product, such as "granular", "WP", or "EC", must be accurate. A wettable powder must contain wetting agents, and an emulsifiable concentrate must contain an emulsifier. Any numbers immediately preceding letters such as "G", "EC", "L", "WP", or "D" have customarily been associated with the percentage or weight of active ingredient of the product; therefore, any number associated with these letters must accurately reflect the composition of the product.

(2) Words or phrases implying that a product possesses unique characteristics because of its composition are not acceptable. Examples of such terminology are, "unique formula," or "strongest on the market." The claim "new" may be used on the labeling of a product of new composition for a period of 6 months following approval of the labeling; however, the word "new" may not be a part of the product name of record.

(3) Vague or non-specific terms implying unstated benefits related to higher concentrations or greater percentage of active ingredient are not acceptable. Examples of such terms include, but are not limited to, "professional strength," "extra strength," "extermination strength," "hospital grade," and "hospital strength."

(4) The term "professional" applied to users is not acceptable unless qualified to describe specifically the professional user group intended. The non-specific phrase "For professional use only" or any variation of that phrase is not acceptable in any circumstances.

(c) *Statements concerning the effectiveness of the product as a pesticide or device.* Claims relating to product effectiveness may not be false or misleading in any particular. Examples of types of statements which are considered to be misleading with respect to any product are given below:

(1) Claims which imply total eradication or elimination of pests, including terms such as "100% effective," "rid," "free," "eliminates," "eradicates," "guaranteed to kill all," "sure kill," "dead sure," "kills virtually all," "weed-free," and "conquers." These and similar terms may be used in conjuntion with sterilizers and disinfectants, or in other circumstances when the claimant is required to provide evidence of complete kill in order to obtain registration.

(2) Claims which imply or state a percentage of pest control which is not valid, such as "kills 90% of [pest]." The claimed levels of efficacy must be determined by product testing.

(3) Terms implying that protection will extend for an indefinite period, such as "bug-proof", "germ-proof", "roach-proof", "mouse-proof", and "long-lasting control". The duration of effectiveness should be established by testing, and included on the labeling.

(4) Non-specific terminology or comparative words without valid comparison, such as "great new weapon," "the most notable advance in pesticides since . . ." "hard-to-kill" (weeds, rats, etc.), and "better and more effective."

(5) Superlatives, such as "perfect," "paramount," "ultimate," "ideal," and "superior," except that such words may be used in the product name when accompanied by the qualifier "Brand," (e.g., "Superior Brand Disinfectant").

(6) Claims for indirect or secondary benefits in the following situations:

(i) Claims implying that benefits will derive solely from use of the pesticide, when other factors contribute in equal or greater measure. An unacceptable claim in this respect is that a product will "improve production" or "produce larger animals."

(ii) Claims of indirect benefits, where the relationship between the direct benefit and the indirect benefit is not clearly established. For example, claims for control of disease vector pests are not acceptable if the conditions of transmission of the disease via the pest have not been clearly established.

(iii) Claims that indirect benefits are direct benefits. For example, labeling may not state that an insecticide will prevent the spread of plant disease viruses (indirect benefit), when in

actuality the pesticide controls the insect host of the virus (direct benefit). Labeling may, however, provide properly worded information on the circumstances under which indirect benefits may be expected. For example, an insecticide labeling may state that the product controls ticks that may transmit Rocky Mountain spotted fever.

(7) Dosages or dilution rates not consistent with package size. Directions for diluting 5 lbs. of product in water are not acceptable on a package that contains only 2 lbs. of product. Similarly, unless otherwise provided in this part, the directions shall not provide for a single application of more product than the package contains.

(8) Illustrations or graphics that imply a greater range of effectiveness than can be demonstrated, e.g., pictures of sites or pests for which the product is not registered.

(9) Illustrations showing exaggerated or undocumented toxic or behavioral effects of the pesticide on the pest, such as depiction of a pest exhibiting physical symptoms not representative of the effects of the product, or an animal repellent showing a dog or cat fleeing in terror from a treated object.

(10) Claims of benefits that are negated or contradicted by other labeling information.

(d) *Statements relating to the non-pesticidal purpose of product.* Labeling may not contain false or misleading statements unrelated to the pesticidal nature of the product. For example, the labeling of a multi-purpose disinfectant-cleaner may not bear false, exaggerated, or misleading claims concerning the cleaning power of the product. Examples of such false or misleading statements are: "Cleans twice as fast as other brands;" and "The most powerful cleansing agent known to man." Similarly, products which are pesticide-drug combinations, pesticide-fertilizer mixtures, or pesticide-nutrient mixtures may not make misleading claims concerning the drug, fertilizer, or nutrient action or value of the product.

(e) *Language stating or implying that the product is recommended or endorsed by any agency of the Federal Government.*

(1) Unqualified phrases such as "approved by * * *" or "recommended by * * *" are not acceptable.

(2) The EPA registration number and EPA establishment number may not be highlighted by type size, placement, color, or prominence so as to imply endorsement by EPA.

(3) References to Federal agencies that do not imply approval or endorsement are acceptable. An example would be "Tuberculocidal—Permitted for use by the Animal Health Programs, Veterinary Service, APHIS, USDA, in official disinfection programs involving domestic animal housing and transportation facilities." An example of an unacceptable statement is: "Product X has been found to be very effective for the control of imported fire ants and Japanese beetle in Federal-State quarantine programs."

(4) The labeling of a product intended for use in USDA-inspected meat and poultry plants, and for which evidence of approval by the Food Safety and Inspection Service (FSIS) has been submitted to the Agency, may include the following statement: "Authorized for use in edible product areas of official establishments operating under the Meat, Poultry, Shell Egg Grading and Egg Products Inspection Programs".

(5) Reference to cooperative extension services or agricultural experiment stations is acceptable under certain conditions. Refer to § 156.72 (i)(4) and (j)(3) for information on these conditions.

(6) The labeling of any product restricted to use by Federal or State authorities must so state.

(f) *A true statement sued in such a way as to give a false or misleading impression.* Labeling statements which are literally true but have the potential for misleading the user constitute misbranding. Examples are given below:

(1) Statements relative to composition indirectly implying safety of the product:

(i) "Contains all natural ingredients."

(ii) Reference to clearances under the Federal Food, Drug and Cosmetic Act.

(2) Superfluous information not relevant to the uses appearing on the labeling, such as:

(i) The statement "oil soluble" on labeling which bears no directions for dilution with oil.

(ii) Claims for pests not found at the use sites on the labeling, such as the inclusion of weeds found only at aquatic sites on a herbicide product bearing no directions for use on aquatic sites. Similarly, claims for pests not found in the United States on a product sold and distributed in the U.S. are considered misleading.

(g) *Claims as to the safety of the pesticide or its ingredients in any form.*

(1) Use of terms and phrases such as "safe," "non-toxic," harmless to pets and humans," "low in toxicity," "will not harm beneficial insects," "no health hazard," and variations or homonyms thereof are not acceptable.

(2) A statement that a product "contains no (name of chemical)" is not acceptable with respect to an active ingredient. The presence or absence of an active ingredient may be ascertained from the ingredients statement.

(3) A statement that a product "contains no (name of chemical)" with respect to an inert ingredient (not separately identified in the ingredients statement) may be permitted (upon written request, and for a limited period of time) if:

(i) The ingredient is the subject of a proposed or final regulation or other written determination based on hazard considerations, which notice prohibits all use, or use in pesticide products specifically; and

(ii) The product may legally be distributed in commerce for a finite period of time, as, for example, the time between issuance of a regulation and its effective date, or the time allowed for distribution of remaining stocks.

(4) Terms such as "non-flammable" and "non-combustible" are generally not acceptable; for exceptions, refer to § 156.58(b).

(5) Terms implying safety to the environment, such as "ecologically compatible", are not acceptable. The term "biodegradable" may be used only in conjunction with a detergent as, for example, "The detergent in this product is biodegradable".

(6) Graphics which negate or contradict required safety statements are not acceptable. Pictures of children or illustrations such as toys or candy which might be appealing to children are not acceptable.

## Subpart B—Product Identification

### § 156.20 Product name.

(a) The label of each individually registered pesticide product shall bear a product name that distinguishes it from all other registered pesticide products of the same producer or registrant. The product name shall appear on the front panel of the label and on any labeling.

(b) The product name shall be descriptive of the product's ingredients, formulation type, quantity of ingredients, or function, or a combination of these. For example, the name Parathion 2–E is suitable for a product containing 2 lbs/gallon of parathion in an emulsifiable concentrate formulation.

(c) A trademark may be used as part of the product name, but if the trademark refers to a particular ingredient in the product, it shall not be used in the name of any product not containing that ingredient.

(d) The letters listed below shall be used in a product name only with the designated meanings:

| | |
|---|---|
| A (or AS) | Aqueous (suspension). |
| D | Dust. |
| E (or EC) | Emulsifiable (concentrate). |
| F | Flowable |
| G | Granular. |
| L | Liquid. |
| W (or WP) | Wettable (powder). |

(e) A number may be used in a product name to distinguish among products or to describe the quantity of an ingredient in the product. If a number is intended to refer to the quantity of an ingredient, it must be consistent with the ingredients statement.

(f) Any product name or additional brand name that has been recorded by the Agency for that product may appear on the label and labeling of the product when sold or distributed.

(g) No name, brand, or trademark under which a pesticide product is marketed or distributed may be false or misleading in any particular. Registration of a trademark with the U.S. Patent Office is not evidence that such trademark is not misleading under FIFRA; a registered trademark name may be in violation of FIFRA. Examples of names that are considered false or misleading include:

(1) A name that implies efficacy against a pest not named on the labeling (e.g., "Roach Killer," if the product is not registered for cockroach control).

(2) A name that implies broader effectiveness or a higher level of efficacy than has been demonstrated (e.g., "Kill All").

(3) A name that is misleading with respect to the composition of the product (e.g., "Malathion 10% WP" must be a wettable power containing 10 percent malathion).

(4) A name that includes words or any variations of words implying safety or non-toxicity of the product, such as "Saf-T."

**§ 156.22 Pesticide type.**

(a) The type of pesticide must be identified on the front panel of the label. Standard and commonly recognized terms shall be used, such as "insecticide", "herbicide", "defoliant", "algicide", "sterilizer", or "bacteriostat." If the product is a combination product, the label must identify all intended use types. If the product is intended for incorporation or impregnation into non-pesticide substances or articles, the label must indicate not only the pesticide type, but also the substances or articles into which it is to be incorporated.

(b) The pesticide type may be stated in one of the following ways:

(1) As part of the product name on the front panel (e.g, "ABC 10% Malathion Dust Insecticide").

(2) As a separate phrase or statement below the product name (e.g., "A bacteriostat for use in the preservation of water-based paints," or simply "An insecticide").

(c) A product for incorporation into non-pesticide substances or articles must use the separate phrase given in paragraph (b)(2) of this section.

**§ 156.24 Identification of registrant.**

(a) *Name*—(1) *Registrant name.* The name of the registrant or distributor (as agent of the registrant) must appear on the labeling of the pesticide product. Both names may appear on the labeling, provided that the name of the registrant for the product is clearly indicated.

(2) *Contact name.* The name required by paragraph (a)(1) of this section should convey sufficient information to allow a user to contact the appropriate department of the firm. It is desirable that a company with several divisions producing pesticides designate the specific division or other entity responsible for the particular pesticide. For example, "Jones Chemical Company, Animal Products Division."

(b) *Address.* (1) The address must provide sufficent information to direct a user to the company. The address must include the city, State and zip code of the company, and a street address. If the street address is contained in the telephone directory of the listed city, a post office box number may be used on labeling.

(2) The registrant may list several addresses, provided the principal address to contact for information regarding the product is clearly indicated.

(3) A foreign registrant must provide the foreign address of the company. Labeling may, in addition, bear the name and address of the U.S. agent for information purposes.

**§ 156.27 Optional identification elements.**

A registrant may include on labeling additional company identification elements, such as company logos, lot or code numbers identifying particular batches of products, dates of label preparation, or the Universal Product Code. Such identification elements shall not detract from or obscure required information.

**§ 156.30 Product registration number.**

(a) *Requirement.* The label must bear the registration number assigned to the product, preceded by the phrase "EPA Registration No." or "EPA Reg. No." The registration number consists of the company number of the registrant followed by a hyphen and a sequential number designating the individual product, e.g., "EPA Reg. No. 9151–156" (company number-sequential product number). The label of a distributor product must bear the registration number of the product, followed by the distributor's company number (company number-sequential product number-distributor company number).

(b) *Location of the registration number.* The registration number must appear on the label and on any labeling for the product. The preferred location on the label is the bottom of the front panel. The number must run parallel to other print, and must be in a type size and style similar to other print on that part of the labeling on which it appears. The registration number may not appear in such a manner as to imply endorsement or recommendation of the product by the Agency.

**§ 156.31 Producing establishment number.**

(a) *Requirement.* Every pesticide product or device shall bear the producing establishment registration number of the final establishment at which the product was produced. (Establishment numbers are assigned upon request to the Agency.) The number shall be preceded by the phrase "EPA Est." or "EPA Establishment." Labeling shall not bear the establishment number of any intermediate establishment.

(b) *Location of establishment number.* The EPA establishment number may be displayed on the label, labeling, or immediate container of the pesticide product. The type size and form for the number must be comparable to that used for the EPA registration number. If the establishment number is placed on the immediate container, it must be on the container itself, and not only on the lid, cap, or any other appendage which is not permanently a part of the container. The establishment number must also appear on the wrapper or outer container if the number on the immediate container cannot be clearly read through such wrapper or outer container.

(c) *Form of the establishment number.* The EPA establishment number shall be expressed as (company number)—(two-letter State designation)—(sequential number within State). An example would be 123–MA–2, indicating the second establishment within the State of Massachusetts for the company whose number is 123. Multiple establishment numbers may be listed, provided that it is clear at which establishment the product was produced. The format of

multiple establishment numbers may be varied with the approval of the Pesticides Branch in the EPA Region where the producing establishment is located. The EPA establishment number may not be combined with the EPA registration number.

**§ 156.34 Ingredients statement.**

(a) *Requirement.* The label must bear a statement of the ingredients in the product. The statement must include the name and percentage by weight of each active ingredient and the total percentage of all inert ingredients (including impurities of the active ingredient), and shall meet the requirements of paragraphs (b) through (h) of this section, as applicable.

(b) *Location of the ingredients statement.* The ingredients statement normally must appear on the front panel of the label. The Agency may, upon written request, grant permission to place the ingredients statement on the back or side panel of the label when the pesticide is packaged in extremely small or irregularly shaped containers, or when the ingredients statement is unusually long.

(c) *Form of the ingredients statement.* (1) The ingredients statement must contain the following items:

(i) The headings "ACTIVE INGREDIENT(S)" and "INERT INGREDIENTS," both aligned to the same left margin, and in the same type size and form.

(ii) The name of each active ingredient, in accordance with paragraph (d) of this section.

(iii) The nominal concentration of each active ingredient and the total percentage of inert ingredients, in accordance with paragraph (e) of this section.

(2) A "blind label," which lists all ingredients in order of descending amount without giving the percentage of each, is not acceptable.

(3) The active ingredients and percentages may be listed in column or, if the label space is limited, in paragraph form. If a column form is used, the percentages shall be aligned according to decimal place. An example of each type follows:

| | Percent |
|---|---|
| Active ingredients | 81.7 |
| Common name (chemical name) | 56.4 |
| Common name (chemical name) | 22.1 |
| Common name (chemical name) | 3.2 |
| Inert ingredients | 18.3 |

Active Ingredients: Common name (chemical name) 56.4%; common name (chemical name) 22.1%; common name (chemical name) 3.2% Total active ingredients 81.7%
Inert Ingredients: 18.3%

(d) *Names to be used in the ingredients statement*—(1) *Common name.* Each active ingredient must be identified by an accepted common name, if there is one, in the order of precedence of use specified in paragraph (d)(2) of this section, followed by the chemical name in accordance with paragraph (d)(3) of this section. An active ingredient never before registered must have a common name for use in the ingredients statement.

(2) *Order of precedence of common names.* The following order of precedence shall be used for common names:

(i) A common name established by the American National Standards Institute (ANSI). Persons wishing to establish a common name should write to the Secretary, K–62 Committee, American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

(ii) A common name established by the International Standards Organization (ISO).

(iii) A common name established by the British Standards Institution (BSI). Information on the International Standards Organization and British Standards Institution accepted common names may be obtained for the British Standards Institution, 2 Park Street, London, England.

(iv) A common name established by an appropriate technical association in the United States, such as the Weed Science Society of America.

(v) A common name established by the Administrator, under FIFRA sec. 25(c)(6).

(3) *Chemical name.* Immediately following the common name, the chemical name must appear. If there is no common name, the chemical name alone must be used. Chemical names must be given according to the nomenclature of the Chemical Abstracts Service of the American Chemical Society. Persons wishing to verify the correct chemical name for an ingredient should write to the Nomenclature Director, Chemical Abstracts Service, The Ohio State University, Columbus, Ohio 43210.

(4) *Descriptive name.* If there is no accepted common name and no specific chemical name for an ingredient, the ingredients statement must contain a descriptive name approved by the Agency. Examples are "derris resins," "tobacco other than nicotine," and "petroleum distillates."

(5) *Trademark name.* A trademark name may not be used in the ingredients statement unless the name has been approved as a common name by the Administrator under the authority of FIFRA sec. 25(c)(6). Trademark names and other information concerning a particular ingredient may appear by reference to a footnote to the ingredients statement.

(e) *Expression of percentages.* (1) The percentage of each active ingredient shall be the nominal concentration. The nominal concentration is the amount of active ingredient in a representative sample of the product produce in accordance with good manufacturing practice by the process described in the application for registration. The nominal concentration will always be within the certified limits for the ingredient. Sliding scales, ranges, or the certified limits, e.g., 23–25 percent, may not be used on the label.

(2) The stated percentage of the total inert ingredients shall be such that the percentages of active and inert ingredients total 100 percent. The term "100%" need not be expressed as part of the ingredients statement.

(f) *Additional statements in the ingredients statement.* (1) If a pesticide contains arsenic in any form, the ingredients statement must contain a substatement of the percentages of total and water soluble arsenic, both expressed as elemental equivalent. Examples of typical wording follow:

(i) "Total arsenic, all in water soluble form, expressed as elemental: ——%."

(ii) "Total arsenic, as elemental arsenic: ——%; Water soluble arsenic, as elemental arsenic: ——%."

(2) The ingredients statement of a product whose active ingredient is a salt, ester, or amine of an acid must include a statement giving the percentage of acid equivalent, an example of which follows:

| | Percent |
|---|---|
| Active ingredient: Dimethylamine salt of 2,4–D * | |
| Inert ingredients | |

* Contains 22.1% acid equivalent of 2,4–D or 2 lbs. 2,4–D acid per gallon
or
* Equivalent to 22.1% 2,4–D or 2 lbs. 2,4–D acid per gallon.

(3) Equivalency statements are useful, but not required for metallic and halogen compounds.

(4) the label shall include a statement of the weight of active ingredient per unit volume of product if the product is intended for agricultural use and the dosages are expressed in volumetric terms. A statement similar to "contains —— pounds of active ingredients per gallon" (or other suitable weight and volume units) is acceptable. The expressed conversions shall be as accurate as is practical. Decimals should

not be rounded to the next highest whole number.

(g) *Identification of inert ingredients.* (1) If the Administration determines by regulations or on a case-by-case basis that any inert ingredient poses a hazard to man or the environment, that ingredient must be identified on the label. A statement in or in close proximity to the ingredients statement similar to, Contains (name of ingredient)" is sufficient. In addition, special precautionary statements may be prescribed with respect to such ingredients. Refer to § 156.50 for a listing of those inert ingredients which must be so identified, and for the specific precautionary labeling required for each.

(2) Except as provided by paragraph (g)(l) of this section, if any inert ingredient is identified on the label, all inert ingredients must be identified in descending order by weight. The percentage of the inert ingredients need not be listed.

(h) *Ingredients statements for products of biological origin.* (1) The ingredients statement for a product whose active ingredient is a biological organism rather than a chemical substance must identify the organism by the most explicit accepted scientific name (genus, species, and strain). The statement must declare the number of viable organisms or colony-forming units (e.g., spores) per unit measures of ingredients. An example follows:

| | Percent |
|---|---|
| Active ingredients: a mixed culture of not less than 100 million viable spores of either *Bacillus popilliae* or *Bacillus lentimorbus* or both per gram of powder | |
| Inert ingredients | |

(2) If the product's action derives from a combination of a biological organism and a toxin of biological origin (e.g., *Bacillus thuringiensis*), or if it is not readily demonstrable whether the active component is a viable organism (e.g., nuclear polyhedrosis virus), the active ingredient must be stated in an acceptable and generally recognized bioassay unit. An example follows:

| | Percent |
|---|---|
| Active ingredient: *Bacillus thuringiensis* Berliner —— International Units of potency per mg. (equivalent to —— billion International Units of potency per pound (quart) of this product | |
| Inert ingredients | |

(3) the ingredients statement for a product whose active ingredient is a naturally occurring plant regulator, for which quantitative chemical methods and units are not available, such as cytokinen, auxin, or gibberellin, must be stated in an acceptable and generally recognized bioassay unit. For example, the active ingredient may be stated as "Cytokinen (equivalent to 200 ppm kinetin activity)" or "Auxin (equivalent to 150 ppm indoleacetic acid activity)."

(4) The Agency may approve alternate forms of ingredients statement for products containing ingredients of biological origin, if such statements are consistent with the purposes of the Act.

(i) *Optional expiration date.* The labeling may bear a date beyond which the product may not legally be sold or used. A statement such as, "Not for sale or use after (date)" may be used for this purpose. The labeling may also bear the date of manufacture of the product as a reference for such a statement, e.g., "Not for sale or use after six months from date of manufacture."

(j) *Optional statement of feed and fertilizer analysis.* A registrant may include in labeling a statement of feed or fertilizer composition, which may vary according to the requirements of individual State laws. The statement must be separate from the pesticide ingredients statement, and must not detract from or obscure the required pesticide labeling statements.

**§ 156.36 Net weight or measure of contents.**

(a) *Requirement.* The net weight or measure of contents of the product must appear on the label or container. The stated net weight or contents must be measured exclusive of container or wrappers and shall be the average content, unless specifically stated to be the minimum content.

(b) *Units of measure.* (1) The net contents may be stated in standard U.S. units, metric units, or both. Either may predominate or be emphasized by means of placement, type size, or form, but the predominant unit must be consistent with the package size unit, e.g., metric units may not predominate on a package containing a quart of product.

(2) Units must be appropriate to the size of the package. For example, a package containing less than one pound, gallon, kilogram or liter must be expressed in smaller appropriate units, e.g., ounces, quarts, grams or milliliters.

(c) *Form of statement.* Unless otherwise specified in this section or by the Agency, any method of expressing the net weight or contents is acceptable.

(d) *Net contents statement for multi-unit packages.* The net contents statement of a multi-unit package containing unit packages (not intended to be sold separately) must include, on the labeling of the outer container:

(1) The number of individual unit packages contained in the package;

(2) The net weight or contents or each unit package; and

(3) The net weight or contents of the total package. For example, a package containing four individual bait boxes may state "4 bait boxes 100 grams each. Total 400 grams." A container of individually wrapped tablets may state "50–15 gm tablets. Total 750 gms." Individual unit packages are not required to bear a net contents statement.

(e) *Location of the net contents statement.* (1) The net contents statement may be located either on the label, labeling, or container. If on the label, the preferred location is the lower third of the front panel. If on the container, it must be in close proximity to the label text, and may not appear only on the top, bottom, or lid of the immediate container or outer container, if there is one.

(2) The net contents of a product being transported or stored in a bulk container must appear on the shipping papers accompanying the product, or on the labeling attached to the bulk container.

(f) *Fair Packaging and Labeling Act.* Any net contents statement that meets the requirements of the Fair Packaging and Labeling Act, as set out in regulations in 16 CFR Part 500, satisfies the requirements of paragraphs (b), (c), and (d) of this section.

(g) *Variations in net content.* Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below that stated average content.

## Subpart C—Warnings and Precautionary Statements

**§ 156.40 Content and format.**

(a) *General.* The label of each pesticide product shall bear warnings and precautionary statements with respect to human, environmental, and physical or chemical hazard posed by the product, in accordance with this subpart. Statements required by this subpart include the signal word, child hazard warning, statements of practical treatment, and general precautionary statements. Required environmental hazard statements include toxicity to nontarget fish, mammals, birds, aquatic invertebrates, beneficial insects, and

plants. Required physical and chemical hazard statements primarily include flammability, but may also include characteristics such as explosiveness, reactivity, or oxidizing capability. The Agency may require on a case-by-case basis, that additional hazard statements appear on the label, such as statements pertaining to chronic hazards.

(b) *Front panel statements.* All required front panel warning statements must be grouped together, must run parallel to other print on the label, and must appear with sufficient prominence to make them unlikely to be overlooked. The signal word and the child hazard warning are subject to the type size requirements specified in Table I of § 156.10. Surrounding the front panel warning statements with a solid line (blocking) is suggested as a means of lending prominence to these statements.

(c) *Side or back panel statements.* Precautionary statements must be grouped together on the label and appear under the general heading "Precautionary Statements." They must be further delineated into "Hazards to Humans and Domestic Animals," dealing with humans, pets, and livestock; "Environmental Hazards," addressing fish, birds, wildlife, aquatic invertebrates, plants, and beneficial insects; and "Physical/Chemical Hazards," including flammability hazards.

(d) *Referral statement.* If precautionary statements, including the Environmental Hazard and Physical and Chemical Hazard statements, appear on panels other than the front panel, the front panel must contain a referral statement in language similar to "See additional precautionary statements on side/back panel." This referral statement may be combined with that required for the Statement of Practical Treatment, if applicable. Any or all precautionary statements may be located in the front panel statements.

**§ 152.42 Toxicity category.**

The label of each pesticide product msut include the warning statement required for the toxicity category to which the product has been assigned, based on its acute toxicity (oral $LD_{50}$, dermal $LD_{50}$, inhalation $LC_{50}$, skin and eye effects). A product is assigned to one of four toxicity categories for each hazard indicator. Table 1 lists the toxicity categories for each acute indicator, and the criteria for each. Category I being of greatest toxicity and Category IV least. The overall toxicity category of the product is determined by the greatest hazard shown for any of the acute indicators listed in the following table:

Table 1—Toxicity Category Criteria

| Hazard indicators | Category I | Category II | Category III | Category IV |
|---|---|---|---|---|
| Oral $LD_{50}$ | Up to and including 50 mg/kg. | >50 thru 500 mg/kg | >500 thru 5000 mg/kg | >5000 mg/kg. |
| Dermal $LD_{50}$ | Up to and including 200 mg/kg. | >200 thru 2000 mg/kg | >2000 thru 5000 mg/kg. | >5000 mg/kg. |
| Inhalation $LC_{50}$ (actual chamber concentration measured for a 4-hour exposure. | Up to and including 0.05 mg/liter. | >0.05 thru 0.5 mg/liter | >0.5 thru 5 mg/liter | >5 mg/liter. |
| Eye effects | Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days. | Corneal involvement or irritation clearing in 8-21 days. | Corneal involvement, or irritation clearing in 7 days or less. | Minimal effects clearing in less than 24 hours. |
| Skin effects | Corrosive (tissue destruction into the dermis and/or scarring). | Severe irritation at 72 hours (severe erythema or edema). | Moderate irritation at 72 hours (moderate erythema). | Mild or slight irritation (no irritation or slight erythema). |

**§ 156.44 Signal word.**

(a) The signal word ("DANGER," "WARNING," or "CAUTION") of the Toxicity Category to which the product is assigned must appear on the front panel of the label beneath the heading "Precautionary Statements" on the side panel as required by § 156.52, and on any labeling. The words "Danger", "Warning", and "Caution" may not appear in labeling in any other location, unless required by the Agency.

(b) The label of a product assigned to Toxicity Category I based on acute oral, dermal, or inhalation toxicity is required to bear the signal word "DANGER". In addition, the word "POISON" (in red) together with the skull and crossbones must appear in close proximity to the signal word.

(c) The label of a product assigned to Toxicity Category I solely on the basis of eye or skin irritation effects is required to bear the signal word "DANGER". The skull and crossbones and word "POISON" are not required for such products.

(d) The label of a product assigned to Toxicity Category II is required to bear the signal word "WARNING".

(e) The label of a product assigned to Toxicity Category III or IV is required to bear the signal word "CAUTION".

(f) The label of a product in any Toxicity Category may not bear the signal word assigned to a category of lesser toxicity, unless the Agency determines that the testing upon which that categorization was based is not truly indicative of the toxicity of the product to humans.

(g) The label of a product in any Toxicity Category may not bear the signal word assigned to a category of greater toxicity, unless the Agency determines that:

(1) The testing upon which that categorization was based is not truly indicative of the toxicity of the product to humans; or

(2) Based on accident reports or other information, the product requires the higher signal word to prevent unreasonable adverse effects.

**§ 156.46 Child hazard warning.**

(a) A child hazard warning statement must appear on the front panel of the label, on a separate line above the signal word, unless a waiver has been obtained in accordance with paragraph (c) of this section. The child hazard warning must also appear in any product labeling. The child hazard warning may not be juxtaposed with the signal word (i.e., WARNING: Keep Out of Reach of Children) so as to give the impression that the signal word applies only to child hazards.

(b) The child hazard warning normally required on products is "Keep Out of Reach of Children." If this warning would not be appropriate because of the circumstances of the intended use pattern, the Agency may permit a child hazard warning that more accurately reflects the form and use of the product. For example, a dog or cat collar, where the normal use of the product permits access by children, may bear the child hazard warning, "Do not allow children to play with collar."

(c) Upon written request of the registrant, the Agency will consider waiving the requirement for a child hazard warning. To support a waiver request, the product must be approved for use by or on small children and infants, or the applicant must demonstrate that the likelihood of contact with children in distribution, marketing, storage, or use is extremely remote.

**§ 156.48 Statement of practical treatment.**

(a) *Requirement.* A statement of practical treatment is required on the label of each pesticide product assigned to Toxicity Category I, II, or III. Instructions must address each route of exposure (oral, dermal, inhalation, eye and skin effects) that assigns the product to Toxicity Category I, II, or III. A statement is not required for any route of exposure in Toxicity Category IV. Instructions for various routes of exposure may be combined when appropriate.

(b) *Placement of statement.* (1) The statement of practical treatment for each route of exposure falling into Category I shall appear on the front panel of the label, grouped with the signal word and child hazard warning. Blocking is suggested as a means of emphasizing the statements.

(2) The statement of practical treatment for routes of exposure not falling into Category I may appear on the front, side, or back panel. In this case, the statements must be set apart from other precautionary statements on the panel. A referral statement on the front panel must be used when practical treatment statements appear elsewhere on the label.

(c) *Format of statement.* (1) The heading "Practical Treatment" or "First Aid" must precede the statement in all cases. The heading "Antidote" shall not be used, unless a specific antidote is recommended.

(2) The statements should be brief and in clear, simple, straightforward language so that the average person can easily and quickly understand the instructions.

(3) The statements should be segregated according to the various routes of exposure. Routes of greater hazard, requiring the most urgent treatment, should be listed first. For example, a product whose primary hazard is eye irritation, with lesser effects from oral, dermal, and inhalation toxicity, should appear as follows:

IF IN EYES, . . . .
IF SWALLOWED, . . . .
IF ON SKIN, . . . .
IF INHALED, . . . .

(d) *Nature of statements.* (1) A recommended practical treatment measure should generally be appropriate for all levels of exposure to the pesticide that result in acute toxic effects.

(2) The statement should be appropriate for persons of all ages who might be expected to be exposed, or should distinguish between treatments for differing ages, e.g., children vs. adults.

(3) The recommended practical treatment should be one that any reasonably competent individual is capable of performing. Procedures for which medical personnel or specialized equipment are required should be reserved for a "Note to Physician."

(4) The treatment should have few or no harmful effects.

(5) If there is a specific antidote for the pesticide, information on its use should be included.

(6) If inducing vomiting is recommended as a practical treatment measure, salt or salt solutions shall not be recommended as the emetic agent.

**§ 156.49 Note to physician.**

A "Note to Physician" must be included on the label for:

(a) All products in Toxicity Category I, and

(b) Any product containing an ingredient that produces physiological effects requiring specific antidotal or medical treatment. Examples of this latter category are cholinesterase inhibitors (such as carbamates and phosphorothioates), metabolic stimulants (such as dichlorophenols), and anticoagulants (such as warfarin). The Note to Physician must appear near the Statement of Practical Treatment, but clearly distinguished from it. Appropriate items for the Note to Physician are technical information on symptomatology, use of supportive treatments to maintain life functions, an medications that may counteract the specific physiological effects of the pesticide. A company telephone number may be provided to give medical personnel access to specialized medical advice.

**§ 156.50 Inert ingredient labeling.**

(a) When an inert ingredient has been determined by the Agency, by regulation or on a case-by-case basis, to pose an acute or other hazard, or to contribute significantly to the overall hazard of the product, the label must:

(1) Identify the inert ingredient by common name, if there is one, or by chemical name, in close proximity to the ingredients statement (a statement such as "Contains———" is acceptable for this purpose);

(2) Include specific precautionary statements required by ths subpart or by the Agency; and

(3) If required by the Agency, include specific practical treatment statements pertaining to the inert ingredient.

(b) Any product containing an inert ingredient listed in Table 1 must include the specified information on the label:

TABLE 1—REQUIRED LABELING FOR INERT INGREDIENTS

| Substance | Limitations | Required labeling |
|---|---|---|
| Carbon tetrachloride | | 1. Identification.<br>2. Skull and crossbones and word POISON in red.<br>3. Statement: "DANGER". May be fatal if swallowed or inhaled.<br>4. Appropriate practical treatment statement. |
| Methanol | 4 percent or more | 1. Identification.<br>2. Skull and crossbones and word POISON in red.<br>3. Statement: "DANGER. Methanol may cause blindness. Fatal if swallowed. Avoid breathing spray mist or vapors. Avoid contact with skin."<br>4. Appropriate practical treatment statement. |
| Petroleum distillates (when inert) | 10 percent or more | 1. Identification.<br>2. Appropriate practical treatment statement. |
| Sodium nitrite | | 1. Identification. |

**§156.52 Human hazard precautionary statement.**

(a) *Heading.* Human hazard precautionary statements must be immediately preceded by the signal word, if the statements appear on other than the front panel, and by the heading, "Hazards to Humans and Domestic Animals." If the use pattern precludes reasonable expectation of exposure to domestic animals, the phrase "* * * and Domestic Animals" may be omitted from the heading.

(b) *Acute hazard precautionary statements.* (1) Tables 1 through 5 illustrate typical human precautionary statements that must normally appear on labels. These tables are organized by route of exposure and Toxicity Category, and include the appropriate signal word and typical statements of practical treatment.

(2) Because these tables do not express all the hazards of specific products, and because toxic effects other than acute effects are not addressed, modification or expansion of precautionary statements may be necessary to reflect specific hazards of a given pesticide product. Tables 1 through 5 follow:

TABLE 1—PRECAUTIONARY STATEMENTS FOR ACUTE ORAL INGESTION HAZARD

| Toxicity category | Signal word | Skull and crossbones and "Poison" required | Precautionary statements | Statements of practical treatment [1] |
|---|---|---|---|---|
| I | | | | |
| $LD_{50}$ up to and including 59 mg/kg | Danger | Yes | Fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. | *If Swallowed:* Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.[2] |
| II | | | | |
| $LD_{50}$ >50 thru 500 mg/kg | Warning | No | May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. | Same as above. |
| III | | | | |
| $LD_{50}$ >500 thru 5000 mg/kg | Caution | No | Harmful if swallowed. Wash thoroughly with soap and water after handling. | Do. |
| IV | | | | |
| $LD_{50}$ greater than 5000 mg/kg | ....do | No | None required | None required. |

[1] Statements of practical treatment will be significantly different for products containing petroleum distillates or which are corrosive since the induction of vomiting may be contraindicated, depending on the overall oral toxicity of the product.

[2] An alternate statment may be used, for example: *"If swallowed:* Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or, if available, by administering syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconscious person."

TABLE 2—PRECAUTIONARY STATEMENTS FOR ACUTE DERMAL ABSORPTION HAZARD

| Toxicity category | Signal word | Skull and crossbones and posion required | Precautionary statements | Statements of practical treatment |
|---|---|---|---|---|
| I | | | | |
| $LD_{50}$ up to and including 200 mg/kg | Danger | Yes | Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse. | *If on skin:* Wash with plenty of soap and water. Get medical attention. |
| II | | | | |
| $LD_{50}$ >200 thru 2000 mg/kg | Warning | No | May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse. | Same as above. |
| III | | | | |
| $LD_{50}$ >2000 thru 5000 mg/kg | Caution | No | Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. | Do. |
| IV | | | | |
| $LD_{50}$ >5000 mg/kg | ....do | No | None required | None required. |

TABLE 3—PRECAUTIONARY STATEMENTS FOR ACUTE INHALATION HAZARD

| Toxicity category | Signal word | Skull and crossbones and "Poison" required | Precautionary statements and requirements | Statements of practical treatment |
|---|---|---|---|---|
| I | | | | |
| $LC_{50}$ up to and including 0.05 mg/l (actual chamber concentration measured for a four-hour exposure). | Danger | Yes | Fatal if inhaled. Do not breathe dust (vapor or spray mist). [Identify specific respiratory protective device approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.] Remove contaminated clothing and wash before reuse. | *If inhaled:* Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention. |
| II | | | | |
| $LC_{50}$ >0.05 thru 0.5 mg/l (actual chamber concentration measured for a four-hour exposure). | Warning | No | May be fatal if inhaled. Do not breathe dust (vapor or spray mist). Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Remove contaminated clothing and wash before reuse. | Same as above. |
| III | | | | |
| $LC_{50}$ >0.5 thru 5 mg/l (actual chamber concentration measured for a four-hour exposure). | Caution | No | Harmful if inhaled. Avoid breathing dust (vapor or spray mist). Remove contaminated clothing and wash contaminated clothing and wash before reuse. | Must be determined on an individual basis, depending on site of use. |
| IV | | | | |
| $LC_{50}$ greater than 5 mg/l (actual chamber concentration measured for a four-hour exposure. | do | No | None required | None required. |

TABLE 4.—PRECAUTIONARY STATEMENTS FOR EYE IRRITATION HAZARD

| Toxicity category | Signal word | Skull and crossbones and "Poison" required | Precautionary statements | Statements of practical treatment |
|---|---|---|---|---|
| I | | | | |
| Corrosive (irreversible destruction of ocular tissue); or corneal involvement or irritation persisting for more than 21 days. | Danger | No | Corrosive.[1] Causes irreversible eye damage. Do not get in eyes or on clothing. Wear goggles, face shield, or safety glasses).[2] Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. | *If in eyes:* Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. *If swallowed:* Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol. *Note to Physician:* Probable mucosal damage may contraindicate the use of gastric lavage. |
| II | | | | |
| Corneal involvement or irritation clearing in 8–21 days. | Warning | No | Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear (goggles, face shield, or safety glasses).[2] Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. | Same as above, except omit Note to Physician. |
| III | | | | |
| Corneal involvement or irritation clearing in 7 days or less. | Caution | No | Causes (moderate) eye injury (irritation). Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. | *If in eyes:* Flush eyes with plenty of water. Call a physician if irritation persists. |
| IV | | | | |
| Minimal effects clearing in less than 24 hours. | do | No | None required | None required. |

[1] The term "corrosive" may be omitted if the product is not actually corrosive, as demonstrated by testing.
[2] Choose appropriate form of eye protection. Recommendation for goggles or face shield is appropriate for industrial, commercial, or institutional uses. Safety glasses may be recommended for residential uses.

TABLE 5—PRECAUTIONARY STATEMENTS FOR DERMAL IRRITATION HAZARD

| Toxicity category | signal word | Skull and crossbones and "Poison" required | Precautionary statements | Statements of practical treatment |
|---|---|---|---|---|
| I | | | | |
| Corrosive (tissue destruction dermis and/or scarring). | Danger | No. | Corrosive. Causes burns. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber golves.[1] Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. | *If on skin:* Wash with plenty of soap and water. Get medical attention. *If swallowed:* Drink promptly a large quantity of milk, egg white gelatin solution, or if thiese are not available, large quantities of water. Avoid alcohol. *Note to Physician:* Probable mucosal damage may contraindicate use of gastric lavage. |
| II | | | | |
| Severe irritatation at 72 hours. (severe erythema or edema). | Warning | No. | Causes skin irritation. Do not get on skin or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. | Same as above, except omit Note to Physician |
| III | | | | |
| Moderate irritation at 72 hours (moderate erythema). | Caution | No | Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. | *If on skin:* Wash with plenty of soap and water. Get medical attention if irritation persists. |

TABLE 5—PRECAUTIONARY STATEMENTS FOR DERMAL IRRITATION HAZARD—Continued

| Toxicity category | signal word | Skull and crossbones and "Poison" required | Precautionary statements | Statements of practical treatment |
|---|---|---|---|---|
| IV<br>Mild or slight irritation at 72 hours (no irritation or slight erythema). | do | No. | None required | None required. |

[1] Need for gloves must be determined on an individual basis. Some products cause blistering if confined under clothing.

(3) If a product exhibits differing degrees of acute effects by several routes of exposure, a composite precautionary statement and statements of practical treatment must be developed by combining the statements from the table.

(c) *Respirator statement.* (1) A respirator statement is required on the label of each end-use product assigned to Toxicity Category I or II on the basis of inhalation toxicity.

(2) The label of a product in Toxicity Category I on the basis of inhalation toxicity must identify and require the use of a specific type of respiratory protective device that will provide protection to those exposed to the pesticide. Specific model designations may also be included. Only respirators jointly approved by the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) under ther provisions of 30 CFR Part 11 for either Supplied Air Respirators (Subpart J) or Pesticide Respirators (Subpart M) may be specified on the label. A list of approved respirators entitled, "NIOSH Certified Equipment List as of (date)," is published periodically by NIOSH. A copy of the latest edition of this publication may be obtained at a charge from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

(3) The label of a product in Toxicity Category II on the basis of inhalation toxicity must bear the statement, "Wear a respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health for pesticide application." The label may also identify a specific model of respirator.

(d) *Optional emergency information.* Emergency information, in addition to that required by this subpart, may be included on the label. Such information may instruct the user how to contact the company or the National Response Center in care of accident, spill, or other emergency. A registrant may include (or the Agency may require) a telephone number for access to emergency information.

**§ 156.55 Environmental hazard statements.**

(a) *Requirement.* Statements pertaining to hazard to fish, mammals, birds, aquatic invertebrates, beneficial insects, and endangered species are required on the label of a product intended for outdoor use. The required statements are based on the results of tests required by 40 CFR 158.145 and 158.155.

(b) *Placement.* (1) A statement that applies to the majority of use patterns on the label should generally appear in the side or back panel Precautionary Statements, under the heading "Environmental Hazards."

(2) A statement associated with a specific use pattern, site of application, application technique, time of application, or geographic location should be placed in the general Directions for Use section, or in close association to the applicable use directions.

(c) *Environmental contamination statement.* (1) Except as provided by paragraph (c)(3) of this section, each product intended for outdoor use must bear the statement "Do not contaminate water by cleaning of equipment or disposal of wastes." This statement must appear in the Precautionary Statements section.

(2) Each product intended for outdoor use (unless application to water or wetlands is specified on the label) must bear the statement, "Do not apply directly to water or wetlands."

(3) Each product for use in cooling towers, pulp and paper mills, or similar sites where the pesticide may be contained in effluent discharges from the site (which may be governed directly or indirectly by the issuance of a National Pollutant Discharge Elimination System (NPDES) permit), is required to bear the following statement:

> Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifiying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

This statement must appear in the general Directions for Use.

(d) *General toxicity statements.* Products intended for outdoor use that exhibit toxicity to various nontarget animals as demonstrated by the toxicity tests required by § 158.145, must bear toxicity statements (which shall be located in the Precautionary Statements section of the label) as follows:

(1) If the mammalian acute oral $LD_{50}$ is 100 mg/kg or less, or the avian acute oral $LD_{50}$ is 100 mg/kg or less, or the avian subacute $LD_{50}$ is 500 ppm or less, the label must bear the statement, "This pesticide [or product] is toxic to wildlife."

(2) If the fish acute $LD_{50}$ is 1 ppm or less, the label must bear the statement "This pesticide [or product] is toxic to fish."

(3) If the aquatic invertebrate acute $LD_{50}$ is 1 ppm or less, the label must bear the statement, "This pesticide [or product] is toxic to aquatic invertebrates."

(4) The term "toxic" in the statements must be replaced with "extremely toxic * * * [Fish and/or wildlife] in treated areas may be killed," if field studies or accident history demonstrates that the use of the pesticide may result in fatality to birds, fish, aquatic invertebrates or mammals. The Agency will apply this requirement on a case-by-case basis.

(5) If the product exhibits toxicity in more than one wildlife or aquatic category, the required statements may be combined i.e., "This pesticide is toxic to fish and wildlife." If a product exhibits toxicity to both fish and aquatic invertebrates, only the statement for fish in paragraph (d)(2) of this section need be used.

(e) *Use restrictions.* The toxicity statements in paragraph (d) of this section are the minimum acceptable for any product requiring environmental hazard statements. If a product is toxic or extremely toxic and an environmental hazard is associated with a specific use pattern, site, application technique, geographic location, or other use-related parameter, use restrictions may be required. Examples of some frequently required statements, together with the conditions that trigger their required use, are given below:

(1) For pesticides with aquatic uses: "Consult your State Fish and Game Agency before applying this product to public waters to determine if a permit is needed for such application."

(2) For granular pesticides that are extremely toxic: "Cover or incorporate granules that are spilled during loading or are visible on soil surface in turn areas."

(3) For products for use on non-aquatic sites that require a toxicity statement under paragraph (d) (2) or (3) of this section: "Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas."

(4) For swimming pool algicides and slimicides containing chlorine: "Chlorine must be allowed to dissipate from treated pool water before discharge. Do not make any chlorine application within 24 hours of discharge."

(5) For products containing instructions for use as seed treatments: "Dispose of excess treated seed by burial away from bodies of water."

(f) *Endangered species.* (1) Based on data submitted in accordance with §§ 158.135, 158.145, and 158.155 and upon recommendations of the Office of Endangered Species, Department of the Interior, or the National Marine Fisheries Service, Department of Commerce, the Agency may require, on a case-by-case basis, specific restrictions for the protection of endangered species.

(2) Statements may take the form of geographical limitations, timing, frequency, or application restrictions, or buffer zones to protect sensitive areas. If required, such statements will be located in the use directions.

(3) In no case may a pesticide label bear directions for use against an endangered species as a pest.

(g) *Beneficial insect cautions*—(1) *Requirement.* Beneficial insect cautions are required on the label of a product if:

(i) The pesticide is toxic to beneficial insects, as shown by data developed in accordance with § 158.155; and

(ii) The product is intended for foliar application to agricultural crops, forests, shade trees or ornamentals, or for mosquito abatement.

(2) *Toxicity criteria.* Pesticide products are classified according to the acute toxicity of their active ingredient(s) to beneficial insects based on data required by § 158.155. The following Table 1 sets out the toxicity groupings and required label statements for honeybees:

TABLE 1.—HONEYBEE TOXICITY GROUPS AND CAUTIONS

| Toxicity group | Precautionary statement if extended residual toxicity is displayed | Precautionary statement if extended residual toxicity is not displayed |
|---|---|---|
| I | | |
| Product contains any active ingredient with acute $LD_{50}$ of 2 micrograms/bee or less. | This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. | This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. |
| II | | |
| Product contains any active ingredient(s) with acute $LD_{50}$ of greater than 2 micrograms but less than 11 micrograms/bee. | This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area. | This product is highly toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area. |
| III | | |
| All others | No bee caution required. | No bee caution required. |

(3) *Precautionary statements.* The appropriate precautionary statement given in Table 1 of this section must be placed in the Environmental Hazards section of the label precautionary statements. The statements in Table 1 are categorized according to toxicity groupings, and further subdivided to delineate products that exhibit extended residual toxicity.

(4) *Use-related restrictions.* Pesticide products that are highly toxic to bees (Group I products) and that bear directions for use on certain specific sites are required to bear additional precautionary statements. These auxiliary statements should appear in the use directions for the particular crop or site rather than in the precautionary statements. Statements are required for the following crops:

(i) Foliar application to alfalfa, peas, or beans: "Do not apply if the crop or weeds in the treatment area are in bloom."

(ii) Foliar application to corn: "Do not apply to corn during the pollen shed period."

(iii) Foliar application to listed fruit trees (apple, cherry, peach, plum, citrus): "Do not apply when trees or substantial numbers of weeds in the orchard (grove) are in bloom."

**§ 156.58 Physical/chemical hazard statements.**

(a) *Flammability statement.* Precautionary statements relating to flammability of a product are required on the label if the product meets the criteria given in Tables 1 or 2 of this section. Tables 1 and 2 also list the statements to be used. These statements are to be located in the side or back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards". No signal word is used in conjunction with the flammability statements. Tables 1 and 2 follow:

TABLE 1—FLAMMABILITY STATEMENTS FOR NON-PRESSURIZED PRODUCTS

| | |
|---|---|
| Flash point at or less than 20°F. | Extremely flammable. Do not use or store near fire, sparks, or heated surfaces. Do not use in the vicinity of pilot lights. |
| Flash point greater than 20°F and less than 100°F. | Flammable. Do not use or store near heat sources or open flame. Do not use in the vicinity of pilot lights. |
| Flash point at or greater than 100°F and less than 150°F. | Do not use or store near heat or open flame. |
| Flash point at 150°F or greater. | No statement required. |

TABLE 2—FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS

| | |
|---|---|
| Flash point at or less than 20°F or if there is a flashback at any degree of valve opening. | Extremely flammable. Do not use or store near fire, sparks, or heated surfaces. Do not use in the vicinity of pilot lights. Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| Flash point greater than 20°F and less than 100°F; or if the flame extension is more than 18 inches at a distance of 6 inches from the flame. | Flammable. Do not use or store near heat sources, sparks, or open flame. Do not use in the vicinity of pilot lights. Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| All other pressurized containers. | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |

(b) *Criteria for declaration of non-flammability.* The label of a product that meets the following criteria for non-flammability may bar the term "non-flammable" or "non-flammable (gas, liquid, etc.)":

(1) If a gas or mixture of gases, it does not ignite when a lighted match is paced against the open cylinder valve.

(2) If a liquid, it has a flash point greater than 350°F (177°C).

(3) If an aerosol, it meets all of the following criteria:

(i) The flame extension is zero inches, and there is no flashback, with the valve opening at a distance of 6 inches from the flame.

(ii) The flash point of the non-volatile liquid component is greater than 350°F (177°C).

(c) *Location of declaration of non-flammability.* The phrase may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) so as to constitute a safety claim.

(d) *Other physical/chemical hazard statements.* When data submitted in accordance with § 158.120 demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard must be included on the label. Such statements may address hazards of explosiveness, oxidizing or reducing capability, reactivity or corrosivity.

## Subpart D—Use Directions and Restrictions

### § 156.60 General.

(a) *Placement*—(1) *Label.* Unless otherwise specified in this section, all information required by this Subpart D may be placed in any location on the label of the product.

(2) *Labeling.* All information required by this Subpart D may appear in labeling (e.g., brochures, pamphlets), instead of on the label, provided that:

(i) Such labeling is securely attached to the pesticide container, or placed within the outer container or wrapper; and

(ii) The label bears a statement similar to, "Use only in accordance with directions in the enclosed circular."

(b) *Heading.* The heading "Directions for Use" or similar wording denoting instruction to the user must be used.

### § 156.62 Classification statement.

(a) *Products classified for restricted use.* (1) If the uses of a product have been classified for restricted use only by certified applicators under FIFRA section 3(d)(1)(C), the label must bear the phrase "RESTRICTED USE PESTICIDE" at the top of the front panel. The phrase must be in capital letters, and must appear in a type size at least as large as that required for the signal word. Type size requirements are found in Table 1 of § 156.10(c)(2). The phrase (and accompanying terms of restriction, if required) must appear prominently above the product name, company logo, or other text or graphic matter so that it is unlikely to be overlooked during the customary conditions of purchase or use. If labeling is also used for Directions for Use, the restricted use phrase and terms of restriction must also appear at the top of such labeling.

(2) If the phrase "RESTRICTED USE PESTICIDE" is required, directly below it must appear a statement of the terms of the restricted use. If use is limited to certified applicators, the statement shall read, "For use only by a certified applicator for uses authorized by his certification, or by persons under his direct supervision."

(3) Blocking the restricted use statements within a solid line is suggested as a means of emphasis.

(b) *Products classified for restricted used and bearing other unrestricted uses.* The label of a product bearing restricted uses may bear unrestricted uses. The product, however, must be labeled in accordance with the requirements of paragraph (a) of this section, as if all uses were restricted. The labeling may not distinguish between uses classified for restricted use and those not so classified.

(c) *Products bearing only uses not classified or classified for general use.* The labeling of a product bearing only uses that are not classified or which are classified for general use may not bear a statement of classification.

### § 156.64 Misuse statement.

(a) The labeling of each product shall bear one of the following misuse statements:

(1) "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(2) "Federal law prohibits use of this product in a manner inconsistent with its labeling."

(b) The misuse statement shall appear as a separate paragraph directly beneath the heading of the Directions for Use portion of the labeling, and shall be distinct from other text in the Directions for Use.

### § 156.67 Worker protection statements.

(a) *Outdoor agricultural products involving hand labor.* The labeling of each product for outdoor agricultural use on crops involving hand labor shall meet the following requirements:

(1) The labeling shall bear the following statement: "Do not apply this product in a manner as to expose workers or other persons either directly or through drift. The area being treated must be vacated by unprotected persons."

(2) If the product is assigned to Toxicity Category I or II, the front panel signal word must appear in Spanish as well as English.

(3) If the product is assigned to Toxicity Category I or II, the statement, "Si usted no lee ingles, no use este producto hasta que el etiqueta haya sido explicado ampliamente," must appear in close proximity to the Spanish signal word. [Translation: "If you cannot read English, do not use this product until the label has been fully explained to you."]

(4) If a specific reentry interval has been established by 40 CFR Part 170, or has been established by the Agency based on data submitted in accordance with Subdivision K of the Registration Guidelines, the labeling must include that reentry interval. A reentry interval established based on data in accordance with Subdivision K takes precedence if there is a conflict with 40 CFR Part 170. The following statement must be used: "Do not enter or allow entry into treated areas within —— (hours/days) after treatment unless protective clothing is worn." [The reentry interval in 40 CFR 170.3(b)(2) or that established by application of Subdivision K is to be placed in the blank space.]

(5) If no specific reentry interval has been established in 40 CFR Part 170 or in accordance with Subdivision K, the following reentry statement must appear in labeling: "Do not enter or allow entry into treated areas without protective clothing until (sprays have dried/dusts have settled)."

(6) Labeling must also include a statement advising that State reentry restrictions may be more stringent than federally-established ones. The following is an acceptable statement for this purpose: "State or local reentry regulations may be more restrictive than those stated on this label."

(7) Labeling must bear a statement prohibiting use unless written or oral warnings have been given to workers in an appropriate language or unless areas to be treated have been posted at usual points of entry. The statement shall require that such posting or warning include, at a minimum, the following information, in an appropriate language:

(i) The signal word and, if required for the product, the skull and crossbones symbol (for posting);

(ii) A statement that the area has been treated with a named pesticide;

(iii) The date of treatment;

(iv) The date or time when safe reentry may be accomplished;

(v) A warning not to enter the treated area without protective clothing until the date specified; and

(vi) A telephone number for further information.

(8) An example of an acceptable posting statement would be, "WARNING. Area treated with (name of pesticide) on (date). Do no enter without protective clothing until (date/time of reentry). For further information call (telephone number)."

(9) Reentry restrictions must appear in the Directions for Use portion of labeling. Specific reentry intervals should be associated with the use(s) to which they are applicable.

(b) *Products for treating structures and vehicles.* The labeling of each product intended for fumigation of structures or vehicles must bear:

(1) A statement requiring the placarding of the treated structure or vehicle at doors and other access points with the following:

(i) The signal word, and, if required for the product, the skull and crossbones symbol;

(ii) The statement "Area under fumigation. Do not enter."

(iii) The date of fumigation;

(iv) The name of the fumigant used;

(v) An emergency telephone number; and

(vi) The name and address of the fumigator.

(2) Complete instructions for aeration of the treated area, including the required use of a suitable detector to determine when the area is safe for reentry.

(3) A statement that the warning placards are not to be removed until aeration has been completed in accordance with the instructions provided.

(c) *Required statement for truck and van fumigants.* The labeling of each product intended for fumigation of trucks, vans and trailers must bear the following statement: "Do not move trucks, vans, or trailers during fumigation. Aerate in accordance with label instructions before moving."

**§ 156.70 Storage and disposal statements.**

(a) *Location and format.* Storage and disposal statements shall be grouped together in the Directions for Use portion of labeling. Products labeled for home and garden use by homeowners only do not require a heading for the statements. All other products shall bear the heading "Storage and Disposal." Storage and disposal statements must be set apart from other directions for use. Blocking is suggested for this purpose.

(b) *Storage instructions.* Labeling must bear storage and handling instructions, based on a consideration of the conditions that might alter the form or composition of the pesticide or that might affect the container and its ability to continue to function properly. Such instruction should describe, when applicable:

(1) Acceptable ranges of temperature and humidity, and the effect of excesses of heat, sunlight, friction or contaminating substances or media on the product;

(2) Acceptable physical conditions of storage of the product, such as positioning of the container, measures to avoid breakage, crushing, shock, friction or moisture penetration, stacking height, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

(3) Proper handling of the pesticide and container, including how to move the container within the storage area, how to open and close the container properly (particularly for partially used containers), and measures to prevent contamination upon opening or closing.

(4) What actions to take if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and what precautions to take to minimize exposure if any of these has occurred.

(5) If the product is for residential or institutional use, instructions for locked storage and warnings against transfer of the pesticide from its original container.

(c) *Pesticide disposal statement.* (1) The labeling of each product intended for residential or institutional use (and in a size appropriate to that use) must bear a disposal statement similar to that for RESIDENTIAL AND INSTITUTIONAL PRODUCTS in Table 1 of this section.

(2) The labeling of each other product that meets any or the criteria in paragraph (c)(2) (i) through (iii) of this section must bear the statement given in that paragraph, together with the pesticide disposal statements given for HAZARDOUS WASTE in Table 1 of this section. If the product meets more than one criteria, it must bear the statement denoting highest hazard (acutely hazardous > toxic > hazardous).

(i) The product is assigned to Toxicity Category I on the basis of acute oral or dermal toxicity, or skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity. Any such product shall bear the statement, "Pesticide wastes are acutely hazardous."

(ii) The product contains any ingredient listed in 40 CFR 261.33(f). Any such product shall bear the statement, "Pesticide wastes are toxic."

(iii) The product meets any of the criteria for a hazardous waste in 40 CFR 261.21 through 261.23, or contains any ingredient listed in 40 CFR 261.24 for EP toxicity. Any such product shall bear the statement, "Pesticide wastes are hazardous."

(3) The labeling of each other product not meeting the criteria of paragraph (c)(2) of this section must bear the pesticide disposal statements given for NON-HAZARDOUS WASTE in the following Table 1:

TABLE 1—PESTICIDE DISPOSAL STATEMENTS

| | |
|---|---|
| Residential and institutional use products. | Securely wrap original container in several layers of newspaper and discard in trash. |
| Hazardous waste | Pesticide wastes are [acutely hazardous/toxic/hazardous]. Dot nof contaminate water, food, or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Dispose of excess or waste pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. |
| Non-Hazardous waste | Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. |

(d) *Container disposal.* (1) If a product is intended and labeled for residential use, its labeling must bear the statement, "Do not reuse empty container (or bottle, can, jar, bag). (If bottle, can, or jar) Rinse thoroughly before discarding in trash. (If bag) Discard bag in trash. (If aerosol) Replace cap and discard in trash. Do not incinerate or puncture." The container disposal statement may be combined with that required for pesticide disposal to eliminate redundancy.

(2) The labeling of each other product must bear a container disposal statement appropriate to the type of container. Unless modifications to statements are approved by the Agency, the statements in the following Table 2 shall be used:

TABLE 2.—CONTAINER DISPOSAL STATEMENTS

| Container type | Disposal statement |
|---|---|
| Metal containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other approved State and local procedures. |
| Plastic containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. |
| Glass containers | Triple rinse (or equivalent). Then dispose of in a sanitary landfill, or by other approved State and local procedures. |

TABLE 2.—CONTAINER DISPOSAL STATEMENTS—Continued

| Container type | Disposal statement |
|---|---|
| Fiber drums with liners..... | Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum cannot by reused[1], dispose of in the same manner. |
| Paper and plastic bags..... | Completely empty bag into application equipment. Then dispose of bag in a sanitary landfill, by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. |
| Large compressed gas cylinders. | Return empty cylinder for refilling (or similar wording). |

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

(e) With the approval of the Agency, alternative statements based on data, or on special packaging types or product characteristics may appear on labeling. Each alternative disposal statement must include a pesticide disposal statement consistent with the requirements of the Resource Conservation and Recovery Act (RCRA), and a container disposal statement also consistent with RCRA requirements.

**§ 156.72 Directions for use.**

(a) *Requirement.* (1) Unless exempted by paragraph (a) (2) or (3) of this section, all end use products are required to bear specific directions or instructions for use, conforming to the requirements of paragraphs (b) through (i) of this section, and of Subpart P of this part in the case of antimicrobial products.

(2) A product limited to use by highly trained professionals such as veterinarians and physicians is not required to bear specific directions for use, provided that:

(i) The label clearly states on the front panel that the product is for use only by veterinarians or physicians;

(ii) The product is also a drug or animal drug that is regulated as such under the provisions of the Federal Food, Drug, and Cosmetic Act.

(3) A manufacturing-use product is exempt from the requirement for detailed directions for use. Refer to § 156.80 for labeling requirements for manufacturing-use products.

(b) *Inclusion of directions for use under a special local needs registration.* (1) A product registered under FIFRA sec. 3 may bear directions for "special local need" uses approved by individual States under FIFRA sec. 24(c), provided that:

(i) Such instructions are clearly distinguished on the labeling from other use directions, such as by enclosing them within a solid outline (blocking);

(ii) The statement, "For use only in (insert name(s) of State)" is included; and

(iii) The special local need (SLN) number assigned by each State in included.

(2) Use directions for special local needs uses must conform to the requirements of §§ 156.72 and 156.76.

(c) *Physical and chemical properties of the product.* In all cases where the pesticide is intended to be incorporated or impregnated into a non-pesticide substance or article, the use directions must include information pertinent to the treatment and use of the finished product into which the pesticide is incorporated. Such information should include:

(1) The physical and chemical properties of the product, such as volatility, stability under conditions of use, photodegradation, or leachability; and

(2) The beneficial results and any detrimental effects that may be expected from the application of the pesticide to the material or article to be treated, such as discoloration, or increased strength, flexibility, or shelf life duration.

(d) *Compatibility with other pesticides.* The use directions should indicate any physical compatibility problems that might be encountered when use with other pesticides in tank mixes is a common practice. If the directions recommend use with fluid fertilizers, a procedure for a "jar" type compatibility test should be included in labeling.

(e) *Adjuvants.* If the product is to be used only with a specific adjuvant, the directions must name that adjuvant, and must provide specific directions for use with that adjuvant.

(f) *Mixing or dilution.* The directions for use must include instructions for mixing or diluting the product unless the product is in a ready-to-use form. Directions for use of any equipment necessary to perform the mixing or dilution must be included. Instructions must include:

(1) Order of mixing, if necessary to proper use;

(2) Identification of the diluent(s) and solvents that may be used, if other than water.

(3) Quantity of each diluent to be used (dilution ratio);

(4) Concentration of final spray;

(5) Need for agitation to maintain suspension;

(6) Special precautions to use when mixing; and

(7) If the container is to be triple rinsed, a statement to add the rinse water to the spray mixture before adding the total volume of water required by the use instructions. The information in paragraph (f) (1) through (7) of this section may appear as general instructions where applicable to all uses, or may be listed separately with each applicable use.

(g) *Sites of applications.* (1) The directions for use must state the site(s) of application, e.g., the crops, animals, areas, or articles to be treated. The site designation must clearly characterize the use pattern so that the Agency can ascertain and evaluate the exposure likely to result from application to that site, and the user can determine the legal use(s) of the product. For example, labeling must distinguish between:

(i) Residential and non-residential sites (e.g., home garden or commercial agricultural application; residential application or institutional application).

(ii) Field and greenhouse sites, if either might reasonably be inferred by the user.

(iii) Indoor and outdoor areas, if either might reasonably be inferred by the user.

(iv) Food crop and non-food crop areas, if either might reasonably be inferred by the user.

(v) Terrestrial and aquatic areas, if either might reasonably be inferred by the user.

(2) If intended for incorporation into non-pesticide items, the ultimate usage of the treated articles or substances, such as "canvas for tents and awnings," or "plastic for non-food, non-human contact articles." All-inclusive or broad terminology without qualification as to the type or ultimate use of the finished product is not acceptable.

(3) The Agency encourages applicants and registrants to consult "EPA Site Categories for Preparing and Coding Pesticide Labeling," a comprehensive listing of acceptable site terminology developed for consistency in characterizing pesticide use sites. Microfiche copies are available at a charge from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. When requesting copies, ask for "Set B of Pesticide Information on Microfiche," NTIS accession number PB80-921900.

(h) *Target pest or objective.* (1) The target pest(s) or intended physiological action must be identified in the directions for use, and generally must be clearly associated with each site to which it applies. In some cases, such as with residential use products, it may be acceptable to group common pests with

a group of sites where those pests may be encountered, if the product is intended for application to each site/pest combination. For example, it may be appropriate to group cabbage looper, imported cabbageworm, and diamondback moth with cabbage, broccoli, brussels sprouts, and cauliflower.

(2) Pests or situations for which the pesticide may be ineffective should be identified. The user should be advised of action to take if ineffectiveness is encountered.

(i) *Dosage rate.* (1) Use directions must specify the effective dosage rate or range for each site and pest combination. If a dosage range is stated, the directions must describe the circumstances in which the higher and lower rates are to be used, as, for example, "Use the higher rate and shortest time interval when heavy pest populations are present," or "Use the lower rate on sandy soils and the higher rate on muck soils."

(2) Dosage rates must be expressed in units of measurement appropriate to the formulation, container size, if necessary, and use site. Examples of appropriate terms would be: amount of product per unit surface area ("1 pound per acre"); amount per unit volume of solvent or diluent, together with total volume to be applied ("One ounce per gallon. Apply to runoff."); duration of exposure at a given concentration ("10 second dip in 0.5% solution"); amount per unit volume of space ("one ounce per 1000 cubic feet"); amount per linear distance ("one pound per 100 feet of row" or "1 oz per 150 feet of row); amount per unit weight ot animal ("one ounce per hundredweight"); or for certain pressurized products, the length of time of spraying at a specified distance from a surface ("10 seconds at a distance of 10–12 inches").

(3) Agricultural pesticides with directions for row treatments must specify the dosage rate in terms of the amount per unit of linear row distance (e.g., "2 oz/1000 linear feet of row") and, when applicable, the band width and row spacing. Row spacings must be stated when the possibility of overlapping treated areas exists. The equivalent amount per unit area for specific row spacing (e.g., "1 pound/acre for 36-inch rows") may be included.

(4) The directions must clearly instruct the user how to achieve acceptable results when the pesticide is applied according to the label dosage rates. However, when a dosage range is provided, the labeling may refer the user to the State Extension Service or State Fish and Game Agency for supplementary guidance in selecting the proper dosage rate within the range for local conditions.

(5) The dosage rate may not exceed the net contents of the product, as packaged.

(6) If the amount of any active ingredient is likely to decrease as a result of deterioration of the product, and the product is intended for use against pests of public health significance, the dosage rate must be adjustable to take this into account. Either of the following is acceptable:

(i) The directions for use may relate dosages to a stated date of manufacture. The use directions may contain a statement such as "If used over —— months after date of manufacture, use an additional —— ounces of product per gallon of water," or the directions may include a table of dosage or dilution variation at periodic intervals after the date of manufacture.

(ii) The directions for use may prescribe the use of test kits or other readily available methods that allow the user to determine the appropriate dosage.

(j) *Timing and frequency of application.* (1) The timing of application, number of applications necessary, and frequency of application must be stated in the directions for use. Dates, number of days before or after planting, last application, emergence or harvest, stage of growth of crop, stage of growth of pest, abundance of the pest(s), indicators of pest appearance, or economic threshold levels may be used to describe timing and frequency of application.

(2) If repeat applications are recommended, directions must include the recommended intervals between treatments (or other indicators of repeat treatment) and the total quantity of product that can legally be applied per growing season.

(3) The directions must clearly instruct the user how to achieve acceptable results when the pesticide is applied according to timing and frequency instructions on the label. However, reference may be made to consult the "State Agricultural Experiment Station, or State Extension Service Specialists" for supplementary information on local pest abundance, integrated pest management procedures, or appropriate local timing of application.

(k) *Method of application.* (1) Clear, specific instructions on how to apply the pesticide are required in the directions for use. Such instructions shall include:

(i) Mixing, dilution, and loading instructions;

(ii) Designation of the type of equipment or apparatus to be used, if necessary for the proper application of the pesticide, or, alternatively, a description of the necessary application parameters, to enable the user to select appropriate equipment for use;

(iii) Calibration instructions for equipment, if necessary;

(iv) Application procedures pertaining to delivery of the proper dosage or dilution coverage and to minimize drift and other undesirable application effects; and

(v) Ancillary procedures to be followed before, during, or after pesticide application so that the user will achieve the intended results, and to minimize exposure to the pesticide. They may include pre-cleaning or preparation of the application site, or watering material into the ground, or sealing the application site (such as with fumigants).

(2) If the pesticide is packaged in or with the apparatus to be used, directions for use of the apparatus must be included. For example, a product used in a pesttrapping device must bear instructions for use of the specified trap, as well as directions for placement of the trap. If the pesticide can be used only with a specific apparatus or type of equipment, the labeling must so state, and provide directions for use of the product with that apparatus.

(3) For agricultural pesticides and those intended for large areas, such as forests, right-of-way, or mosquito abatement, the directions must provide separate directions for ground and aircraft application. Ground instructions must specify the type of ground application equipment (hydraulic, air blast). Aircraft instructions must state whether fixed-wing or helicopter (rotary-wing) aircraft are to be used. Special methods, such as irrigation system applications, must also be separately described.

(4) If aerial application is not intended, and specific directions provided, the labeling must bear a statement prohibiting such application.

**§ 156.76 Restrictions on use.**

The directions for use must include any prohibitions, warnings, or restrictions on use necessary to prevent unreasonable adverse effects or ineffectiveness, or to ensure that residue tolerances will not be exceeded. Such statements may be located in the general directions for use if of general applicability to the use of the pesticide, or in close proximity to the specific directions for the use.

(a) *Preharvest or preslaughter interval.* The interval (time period) between application of a pesiticide on a crop, animal, or site, and its safe harvest

or use for feed or food is required to appear on labeling when data indicate that, without such restrictions, illegal residues may result from use of the pesticide. The interval is generally expressed in a statement such as "Do not apply within 8 days of harvest" or "Withdraw animals from treatment one week prior to slaughter."

(b) *Rotational crop restrictions.* (1) The labeling must include a restriction limiting rotation (or replanting after crop loss) for a specified period of time after pesticide application (not to exceed 18 months) if data submitted in accordance with § 158.26 indicate that:

(i) Residues remaining in soil will result in adverse effects to following crops; or

(ii) Residues remaining in soil will result in residues in the following crop where there is not tolerance, or in excess of an established tolerance for the following crop.

(2) An example of a typical statement would be "Do not plant crops other than corn or sorghum within 12 months after application."

(c) *Geographic restrictions.* (1) Geographic restrictions may be necessary in any of the following situations:

(i) Efficacy testing indicates that the product is not effective in all areas of the country. Statements may limit use to regions or States where effectiveness has been demonstrated, e.g., "For use only in Louisiana, Texas, Arkansas, and Mississippi," or "Southeastern U.S. only."

(ii) An endangered species, or the critical habitat of an endangered species, would be jeopardized by use of the pesticide as proposed on the label. Endangered species restrictions prohibit use in specific counties or other narrowly drawn geographical areas where the endangered species would be jeopardized.

(iii) Residue data submitted in support of a tolerance are not representative of all areas where the crop is grown, or indicate that residues may exceed the established tolerance level in particular areas.

(iv) Data indicate that, without geographical restrictions, unreasonable adverse effects on the environment, such as groundwater contamination may result.

(2) Upon written request, and with the approval of the Agency, the label may bear geographic restrictions desired by the registrant.

(d) *Phytotoxicity (crop safety) warnings.* (1) A statement similar to "Since phytotoxicity has not been evaluated on all possible crop varieties, it is recommended that varietal responses be tested on a few plants prior to full scale applications" should be included in use directions for products intended for use on crops or crop planting sites, if applicable.

(2) When temporary crop injury such as stunting, discoloration, or malformation would be expected to occur, the use directions must advise the user of this expected injury. When some degree of crop stand loss results from pesticide application, even if such loss is considered economically acceptable, this effect must be clearly indicated in the use directions.

(e) *Performance restrictions.* If specific environmental conditions, such as cultural, crop management or chemical use practices, would detrimentally affect product performance, the labeling must identify the conditions and the expected effects. Conditions may include soil conditions, (moisture, pH, texture, organic matter), meteorological conditions, (precipitation, drought, temperature, wind) and cultural practices (tillage, cultivation, irrigation).

(f) *Nontarget area plant cautions.* If a pesticide is readily transported during or after application to nontarget areas through air (via spray drift, volatilization) or water (via leaching, lateral movement in soil, runoff, drainage or irrigation), and has been shown to possess phytotoxic properties, label precautions on possible adverse effects to nontarget plants are required. The nature and duration of any effects (temporary, permanent, or seasonal) should be described.

(g) *Spray drift restrictions*—(1) *General.* When drift may cause adverse effects which the Agency deems significant on organisms outside the intended site of application, either directly or indirectly through contamination of the soil or water, the labeling must advise the user of these effects and must provide recommendations to minimize drift and drift hazard. Drift-related use directions, recommendations, precautions, and limitations should be included for all pesticides applied by, but not limited to, aerial, mist blower, sprinkler irrigation and hydraulic ground applications.

(2) *Content.* Use directions should describe general meteorological conditions, recommended equipment operation and adjustments, and adjuvants and carriers necessary to minimize pesticide drift.

(3) *Specific statements.* General use directions must include the following statements:

(i) For all outdoor applications of sprays and dusts: "Do not apply when weather conditions favor drift from the target area. Coarse sprays are less likely to drift. Increase spray volumes by increasing nozzle orifice diameter rather than by adding more nozzles or increasing nozzle pressure."

(ii) For aerial applications: "Do not use nozzle cores which disperse spray into fine or mist droplets. For crosswind swath applications, begin the first swath on the downwind side of the treatment area, with successive swaths progressing upwind."

(iii) For aerial applications and mist blowers (air carriers): "Do not apply when temperature inversion ceilings are likely to exist."

## Subpart E—Specialized Labeling

### § 156.80 Manufacturing use products.

(a) *General.* This section prescribes requirements for labeling of manufacturing use pesticides. Unless otherwise stated in paragraphs (b) through (n) of this section, the requirements of Subparts A through D apply to all manufacturing use products. The general requirements are enumerated here for reference.

(b) *Name, brand, or trademark.* The requirements of § 156.20 apply.

(c) *Identifying phrase.* An identifying phrase must appear beneath the product name. The phrase must indicate that the product is only for formulation of other pesticides and the type of pesticide (insecticide, for example).

(d) *Name and address of the registrant.* The requirements of § 156.24 apply.

(e) *EPA registration number.* The requirements of § 156.30 apply.

(f) *EPA establishment number.* The requirements of § 156.31 apply.

(g) *Ingredients statement.* The requirements of § 156.34 apply.

(h) *Net contents.* The requirements of § 156.36 apply.

(i) *Precautionary statements.* (1) Except as specified in paragraph (i) (2), (3), and (4) of this section, the requirements of Subpart C apply.

(2) The child hazard warning "Keep Out of Reach of Children" is not required on the label of manufacturing use product.

(3) If all precautionary statements are grouped together on the front panel, the heading "Precautionary Statements" and the signal word required by § 156.52 below that heading may be omitted. The referral statement may be omitted if all precautions appear on the front panel.

(4) The environmental hazard statements required under the heading "Environmental Hazards" are limited to the following:

(i) A statement of relative toxicity to appropriate organisms for hwich testing required by 40 CFR 158.145 indicates a potential hazard, e.g., "This product is toxic to fish and wildlife."

(ii) The statement, "Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."

(j) *Classification statement.* No statement of use classification with respect to use by certified applicators is required or permitted on the labeling.

(k) *Misuse statement.* The misuse statement must appear on the label of a manufacturing use product. The misuse statement must also appear in any labeling in which instructions for formulation appear, located immediately following the heading for such instructions. The wording of the misuse statement is the same as that given in § 156.64.

(l) *Reentry interval statement.* No reentry interval statement is required on the labeling of a manufacturing use product.

(m) *Directions for use.* Detailed instructions for formulating may be omitted from the labeling of a product intended for formulating other registered pesticides, provided that:

(1) The labeling includes the following:

(i) Information pertinent to the needs of the formulators, including, but not limited to, physical and chemical properties, of the product. If such information is stated in labeling rather than directly on the product label, a reference statement such as "Refer to Technical Bulletin X for formulating and other information" must appear on the label.

(ii) A statement that each formulator is responsible for obtaining EPA registration for his end use product(s). Labeling for the manufacturing use product may include sample labels of registered end use products as quidance for formulators. Labeling may not include specimen labels for end use products not registered by the Agency.

(2) Information on the composition, toxicity, methods, of formulation, limitations and restrictions, and effectiveness of the product for pesticide purposes is readily available to the formulator from sources other than the labeling.

(n) *Storage and disposal statements.* The labeling of a manufacturing use product is required to bear appropriate statements of pesticide storage and disposal. Refer to § 156.70 and Tables 1 and 2 of that section for requirements.

**§ 156.87 Unit packaging.**

(a) *Requirement.* Each unit package shall bear a label conforming to the requirements of paragraph (b) of this section. The outer container in which the unit packages are distributed and sold shall bear labeling conforming to the requirement of paragraph (c) of this section. An individual water-soluble unit package which is further enclosed in a foil or plastic wrapper on a one-to-one basis may be labeled on the foil or plastic wrap.

(b) *Contents of label of unit package.* The label of each individual unit package shall include the following information:

(1) A statement of the active ingredient(s). Each active ingredient must be identified by name, unless the Agency has approved a statement including only the names of the principal or most hazardous ingredient(s). The statement of active ingredients need not meet the requirements for an ingredients statement of § 156.34, but may simply declare "Contains (name of ingredient)." No percentages or statements of inert ingredients are required.

(2) The appropriate signal word.

(3) The skull and crossbones (if required).

(4) The child hazard warning, "Keep Out of Reach of Children."

(5)The EPA Registration Number.

(6) The phrase "RESTRICTED USE PESTICIDE" if the product has been so classified.

(7) A reference statement to the label of the outer package for directions and precautions.

(c) *Contents of label of outer container.* The outer container label or labeling must fully comply with the requirements of Subparts A through D. In addition, the front panel of the container must bear the following statement in a prominent position: "Do not remove packages from container except for immediate use."

(d) *Prominence and optional information.* The information required by paragraph (b) of this section must appear in type of 2 mm or greater. The manufacturer may, at this option, add additional information on the unit package when size permits, providing it does not detract from the prominence or legibility of the required information.

## Subpart F—Labeling of Products not Required to be Registered

**§ 156.105 Products shipped between registered establishments.**

(a) *General.* 40 CFR 152.30 exempts from the registration requirement certain pesticides being transferred between registered establishments. Such unregistered pesticides are subject to certain misbranding provisions of FIFRA sec. 2(q). This section sets out the labeling requirements for such products.

(b) *Contents of label.* The label shall bear each of the following items.

(1) The name and address of the producer of the pesticide being shipped, meeting the requirements of § 156.24.

(2) The establishment number of the producing establishment from which shipped. This number is not necessarily the same establishment number as that which will appear on the final product being produced at the second establishment. A product produced at Establishment A and shipped to Establishment B for further formulation and then to Establishment C for packaging into the retail product must bear, successively:

(i) The number of Establishment A during transport to Establishment B.

(ii) The number of Establishment B during transport to Establishment C; and

(iii) The number of Establishment C, the final establishment, on the retail package.

(3) An ingredients statement complying with the requirements of paragraph (b)(3) (i) or (ii) of this section.

(i) If the product is being shipped in final form, i.e., no further formulation or composition changes are to be made prior to distribution or sale of retail packages, the ingredients statement shall comply in all respects with § 156.34.

(ii) If the pesticide is being shipped for further formulation or processing, the ingredients statement shall include the name of each active ingredient, and the percentage of each to the nearest whole percentage.

(4) The net weight or measure of the contents of the product, consistent with the requirements of § 156.36.

(5) Hazard warning statements, conforming to the requirements of Subpart C with respect to signal word, use of the word "POISON" and skull and crossbones symbol and human, environmental, and physical/chemical hazard statements.

(c) *Exemption from requirement for directions for use.* Specific directions or restrictions on use, formulation, or packaging of the product being shipped

between registered establishments are not required to appear on labeling.

(d) *Additional labeling requirements.* The following sections of this part apply to products being shipped between registered establishments.

(1) Section 156.7, Placement of label.

(2) Section 156.10 (a)(3), (b)(1), (c)(1), and (d), concerning prominence, legibility, contrast, type size, and language to be used.

(3) Section 156.15, False and misleading statements, except for paragraph (a), Warranty disclaimer statements.

**§ 156.110 Products for export only.**

(a) A pesticide product, device, or active ingredient used in producing a pesticide that is intended solely for export must be labeled with the following information:

(1) In English or the language of the importing country:

(i) The name and address of the registrant, or if unregistered, or the producer, in accordance with § 156.24;

(ii) The producing establishment number, in accordance with § 156.31;

(iii) A statement of net weight or contents, in accordance with § 156.36; and

(iv) A statement of use classification, if classified for RESTRICTED USE on the basis of toxicity to man or the environment. The terms of the U.S. restriction need not be included.

(2) In English and the language of the importing country:

(i) An ingredients statement, in accordance with § 156.34;

(ii) Warning or precautionary statements, in accordance with Subpart C of this part;

(iii) If in Toxicity Category I on the basis of acute oral, dermal, or inhalation toxicity, the following:

(A) The skull and crossbones (in red or black);

(B) The word POISON (in red) on a background of distinctly contrasting color; and

(C) A statement of practical treatment, in accordance with § 156.48.

(iv) If the product is unregistered, the statement, "Not registered for use in the United States of America."

(b) Labeling of a registered product will be considered to satisfy the requirements of paragraph (a)(1) of this section and the English language requirements of paragraph (a)(2) of this section if the label or labeling otherwise complies with the requirements of this part.

(c) If the information required by this section would conflict with the requirements of the importing country, any or all of the information may instead be included in labeling that is attached to or accompanies the product container or shipping container, provided that the product is labeled according to the requirements of the importing country.

**§ 156.112 Products shipped under an emergency exemption.**

(a) *Registered product.* A registered product must bear the labeling approved in conjunction with its registration.

(b) *Unregistered product.* An unregistered product must bear labeling that complies with the specifications in the authorizing exemption notice. Such labeling will normally be one of the following:

(1) Labeling meeting the requirements of Subparts A through D of this part, but not including §§ 156.72, Directions for use, and 156.76, Restrictions on use;

(2) Labeling approved in conjunction with the issuance of an experimental use permit under FIFRA sec. 5; or

(3) Labeling reviewed and approved by the Agency in conjunction with the request for exemption.

(c) *Directions for use.* (1) In all cases, directions for use of the product must be in accordance with the terms and conditions of the authorizing exemption notice, and must be available to the user at the time of use. Use directions may be contained in labeling (which may include the authorizing exemption notice itself) distributed with the product.

(2) The use directions should include the year or growing season for which use is authorized, and the name of the State to which the exemption has been granted.

**§ 156.115 Pesticides shipped for disposal only.**

(a) *General.* FIFRA section 19 provides that the Administrator shall, if requested by the owner of a pesticide, arrange for disposal of a pesticide that has been cancelled following suspension under FIFRA section 6(c). Regulations contained in 40 CFR Part 165, Subpart B, provide that the owner of the pesticide must transport the pesticide to an acceptance location for transfer to the Agency.

(b) *Labeling requirements for a product being shipped for disposal.* A product being shipped to an acceptance location by its owner, and thereafter being shipped by the Agency to a disposal site, shall bear a label containing the following information:

(1) The name and address of the registrant, or if unregistered, the producer of the product, in accordance with § 156.24;

(2) The establishment number, if any, of the establishment at which the product was produced, if the product remains in the original unbroken container, or at which the product was repackaged for disposal, if the contents have been transferred to another container for disposal purposes.

(3) An ingredients statement, in accordance with § 156.34.

(4) Warning and precautionary statements, in accordance with Subpart C of this part, including the following:

(i) The signal word;

(ii) If highly toxic (Toxicity Category I) by virtue of acute oral, dermal or inhalation toxicity, the skull and crossbones and the word "POISON" (in red), together with an appropriate statement of practical treatment or first aid; and

(iii) Precautionary statements addressing the human, environmental, and physical or chemical hazards of the product.

(5) A statement, that shall at least partially obliterate any directions for use on the label, that the product is for disposal only and not for pesticide use.

(6) If the product is a hazardous waste, as defined by 40 CFR 261.11, or as listed in § 261.33 (e) or (f), it shall also bear the statement in 40 CFR 262.32, i.e., "HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency." A sticker or additional labeling may be used for this purpose.

(7) The required information must not be false or misleading in any particular, and must meet the prominence requirements of § 156.10.

(c) The label of a product for disposal only is acceptable if the labeling meets the requirements of Subparts A through D of this part and it bears the disposal statements given in paragraph (b) (5) and (6) of this section.

**§ 156.118 Pest control devices.**

(a) *Defintion.* A pest control device is any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest. Equipment used for the application of a pesticide, when sold separately from such pesticide, is not considered to be a device. Examples of devices subject to the labeling requirements of this section are electromagnetic and ultrasonic pest control devices, and "glue boards."

(b) *Exemption.* The following devices are exempt from the requirements of this section:

(1) Those that depend for their effectiveness more upon the performance of the person using the

device than on the performance of the device itself, such as rat and mouse traps, fly swatters, and tillage equipment for weed control.

(2) Those that operate only to entrap vertebrate animals, such as fish traps.

(c) *Required labeling information.* The following information must be included on each device, its wrapper, or its package:

(1) *Name, brand or trademark.* The label of a device whose function is not obvious must include a name, brand or trademark, and an indication of the function of the device.

(2) *Name and address of the producer or distibutor.* The name and address of the producer of the device must be provided on the label. Refer to § 156.24 for further information on name and address requirements.

(3) *EPA establishment number.* The label of each pest control device must bear the establishment registration number assigned under FIFRA section 7. This number may appear in any location on the label or on the device itself. If the device is contained in a wrapper or outer container through which the establishment number cannot be clearly read; the establishment number must also appear on such outer container or wrapper. Refer to § 156.31 for further information on the display of the EPA establishment number. The establishment number may not be highlighted or emphasized by size, color or typography to imply Agency approval or endorsement.

(4) *Precautionary statements.* The label must identify any hazards posed in using the product, and must provide adequate warnings and use limitations that, if adhered to, will protect against or minimize such hazards. Hazards may include, but are not limited to, structural (such as sharp edges), mechanical (such as rapidly moving parts), electrical, high temperature, radiation, chemical, or noise.

(5) *Directions for use.* Directions for use of the product must include, at a minimim, the following information:

(i) *Site of use.* Where the device is intended to be used, positioned, or located.

(ii) *Activation.* Instructions on how to install or activate, and, if necessary, deactivate the device if it would not be self-explanatory or obvious to the user.

(iii) *Target pest.* The pest(s) the device is intended to destroy, capture, repel, or affect, and the results that may be expected (death, entrapment, repellency, inactivation).

(iv) *Restrictions or limitations on use.* Any specific circumstances under which the device should not be used, or that would limit the effectiveness of the device. If the duration of the effectiveness is limited, the length of time the device can be expected to be effective must be indicated. If the product would not be effective in certain situations that might reasonably be encountered in use, a statement to this effect must be included.

(d) *False and misleading statements.* The labeling of a pest control device shall not contain any statement that is false or misleading in any respect. Examples of false and misleading statements may be found in § 156.15.

## Subparts G Through O—[Reserved]

## Subpart P—Labeling Requirements for Certain Antimicrobial Products

### §156.300 Sterilizers for use on hard surfaces.

Product labeling may bear "sterilizer" or "sporicidal" claims if:

(a) The product meets the standard in paragraph (b) of this section, when tested by at least two laboratories,one of which is independent of the registrant; and

(b) The product, when tested by the method in § 91–2(a) of Subdivision G of the Registration Guidelines or its equivalent, kills the test spores on all 720 carriers used in the tests.

### § 156.305 Disinfectants for use on hard surfaces.

(a) *Performance requirement.* Product labeling may bear claims as a "disinfectant" if, when tested by the appropriate method in section 91–2 (b), (c), or (d) of Subdivision G of the Registration Guidelines or its equivalent, kills the test microorganisms on 59 out of 60 carriers of each set to provide significance at the 95 percent confidence level.

(b) *Limited efficacy claims.* The labeling of a disinfectant which is effective against specific microorganisms only (e.g. Herpes virus, influenza virus, cold (rhino) viruses) must clearly denote these limitations. Furthermore, such limitations must be readily understandable and shall not be misleading to the user.

(c) *General or broad-spectrum efficacy claims.* Labeling claims of effectiveness as a "General Disinfectant" and representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative test microorganisms.

(d) *Hospital or medical environment efficacy claims.* Labeling claims for use on surfaces in hospital or medical environments will be accepted only for those products that have been demonstrated to be effective for general or broad-spectrum disinfection (see paragraph (c) of this section) and additionally against *Pseudomonas aeruginosa.* Claims such as "hospital disinfectant" or "for hospital use" are acceptable. Claims such as "hospital grade" or "hospital strength" are not acceptable.

### § 156.310 Fungicides for use against human pathogenic Fungi.

(a) *Performance requirement.* Product labeling may bear claims of effectiveness against pathogenic fungi if the product kills all fungal spores by one of the following test methods:

(1) The AOAC Fungicidal Test (see section 91–2(e)(1) of Subdivision G of the Registration Guidelines) or its equivalent; or

(2) The AOAC Use Dilution Method or AOAC Germiciadal Spray Products Test, modified to conform to appropriate elements of the AOAC Fungicidal Test (see § 91–2(e)(3) of Subdivision G of the Registration Guidelines) or its equivalent.

(b) *Claims against pathogenic fungi.* The statement that a product is effective against "athlete's foot" is not acceptable. If the product is effective against the causative organism (*Trichophyton mentagrophytes*) in appropriate areas such as shower room floors, locker room benches, or bath mats, the label may bear a statement such as "kills athlete's foot fungi on inanimate surfaces."

### § 156.315 Virucides.

(a) *Performance requirement.* Product labeling may bear claims as a "virucide" against designated human pathogenic viruses if, when tested according to the method in section 91–2(f) of Subdivision G of the Registration Guidelines or its equivalent, the product:

(1) Inactivates the virus at all dilutions when no cytotoxicity is observed in the assay system; or

(2) Reduces the viral titer by at least a 3–log magnitude when cytotoxicity is observed in the assay system.

(b) *Virucidal claims.* The unqualified claim "virucidal" is not acceptable. The claim "virucidal" must be qualified by designating each specific virus against which the product has been tested and shown to be effective, and to indicate that the activity occurs only on inanimate surfaces.

### § 156.320 Tuberculocides.

(a) *Performance requirement.* Product labeling may bear claims as a "tuberculocide" against *Mycobacterium*

*tuberculosis* if, when tested by the appropriate method in section 91–2(g) of Subdivision G of the Registration Guidelines or its equivalent:

(1) The product kills the test microorganisms on all carriers; and

(2) No growth occurs in any of the inoculated tubes of the two additional required media.

(b) *Tuberculocidal claims.* The labeling of a product claiming disinfection of inhalation therapy equipment and pulmonary diagnostic equipment but which has not been tested for effectiveness against *Mycobacterium tuberculosis* must bear the following statement: "This product has not been tested for effectiveness against *Mycobacterium tuberculosis*, and must not be relied upon when a tuberculocidal product is desired."

**§ 156.325 Phenol coefficient.**

The phenol coefficient, as determined by the AOAC Phenol Coefficient Test in section 91–2(h) of Subdivision G of the Registration Guidelines or its equivalent, is permitted to appear on labeling only if:

(a) The product is a disinfectant, with use directions adequate to support a disinfection level of antimicrobial activity; and

(b) The phenol coefficient, when multiplied by 20, provides the effective use dilution of the product [as confirmed by the AOAC Use-Dilution Method (see section 91–2 (a), (b), or (c) of Subdivision G) or its equivalent]; and

(c) The phenol coefficient is determined on the pesticide as formulated, rather than the active ingredient(s).

**§ 156.330 Products for use against other microorganisms.**

(a) *Performance requirement.* Product labeling may bear disinfectant claims against specific microorganisms other than designated test species if, when tested by the appropriate method of section 91–2(i) of Subdivision G of the Registration Guidelines or its equivalent:

(1) The product kills the test microorganism on all carriers; and

(2) Plate count data on appropriate culture media demonstrate that a concentration of at least $10^4$ microorganisms survived the carrier drying step in untreated controls.

(b) *Claims against other microorganisms.* Substantiated claims of effectiveness of a product against specific microorganisms other than the designated test microorganism(s) are permitted, but not required, provided that the target pest is likely to be present in or on the recommended use areas and surfaces and thus may present a potential problem.

**§ 156.335 Sanitizers for hard non-food contact surfaces.**

(a) *Performance requirement.* Product labeling may bear "sanitizing" claims for use on non-food contact surfaces if, when tested by the method in section 91–2(j) of Subdivision G of the Registration Guidelines or its equivalent, the product achieves a reduction of at least 99.9 percent over the parallel control count.

(b) *Claims.* The labeling of a product intended for use on non-food contact surfaces which does not eliminate, but significantly reduces, the numbers of target microorganisms must be clearly represented and qualified as being effective at the sanitizing level only. Examples of acceptable labeling claims are: "Sanitizes", "Significantly reduces", or "Reduces the number of bacteria by 99.9%." Products recommended for use in critical hospital or medical environments that are not effective at the sterilizing or disinfecting level must bear a labeling disclaimer statement such as: "This product is not a disinfectant or sterilizer".

(c) *Fogging applications.* Representations such as "germicidal fogging" and "disinfectant fogging" are not acceptable. Claims for fogging applications of disinfectants to sanitize room surfaces are acceptable.

(d) *Circulate-in-place (CIP) applications.* Claims for CIP applications as "germicidal" or "disinfecting" are not acceptable. Claims for CIP applications to sanitize the surfaces of the systems are acceptable.

**§ 156.340 Sanitizers for hard food contact surfaces.**

(a) *Performance requirement*—(1) *Halide chemical products.* The labeling of a product formulated with iodophors, mixed halides, or chlorine-containing chemicals may bear claims for "sanitizing" food contact surfaces if, when tested by the method in section 91–2(k)(1) of Subdivision G of the Registration Guidelines or its equivalent, the product concentrations show equivalence of activity to 50, 100, and 200 ppm of available chlorine. (The test standard is sodium hypochlorite.)

(2) *Other chemical products.* The labeling of a product formulated with other chemicals, such as quaternary ammonium compounds, anionic detergent-acid compounds, and chlorinated trisodium phosphate, may bear claims for "sanitizing" food contact surfaces if, when tested by the method in section 91–2(k)(2) of Subdivision G of the Registration Guidelines or its equivalent, the product achieves a 99.999 percent reduction in the number of each test microorganism within 30 seconds.

(b) *Claims.* Claims for a use pattern of "one-step" cleaning and sanitizing are not acceptable for food-contact surfaces.

**§ 156.345 Products providing residual activity for use on hard surfaces.**

(a) *Performance requirement.* Product labeling may bear residual "self-sanitizing" claims (that can be identified as related to human health) if, when tested by the criteria in section 91–2(m) of Subdivison G of the Registration Guidelines or its equivalent, the product achieves at least a 99.9 percent reduction in numbers of test microorganisms on the treated surface(s) over those on the parallel control surface(s).

(b) *Claims.* Label claims pertaining to residual "self-sanitizing" or "bacteriostatic" surfaces (i.e., reduction in numbers, or inhibition of the growth, respectively, of specific microorganisms that may be present or that may be subsequently deposited on hard surfaces) must be related to the presence of moisture on surfaces that are likely to become wet under normal conditions of use. Labeling must also indicate the duration of effectiveness of the treatment. Only self-sanitizing claims can be identified as related to human health considerations.

**§ 156.350 Laundry additives.**

(a) *Disinfecting pre-soak*—(1) *Performance requirement.* Product labeling may bear claims as a "disinfectant" for pre-soaking fabrics prior to laundering if, when tested by the AOAC Use Dilution Method as described in section 91–2 (b), (c), or (d) of Subdivision G of the Registration Guidelines (modified to include organic soil as in section 91–30(e)(4) of subdivision 5) or its equivalent, the product kills the test microorganisms on 59 out of 60 carriers of each set.

(2) *Claims.* Labeling must distinguish between products recommended as soaking treatments prior to laundering and products recommended as additives in actual laundry operations. Pre-soaking claims are applicable only to products which have been shown to be effective as "one-step" cleaner-disinfectants for hard surfaces in the presence of moderate amounts of organic soil (e.g., "pre-soak diapers for 10 minutes to disinfect").

(b) *Non-residual laundry additives*—(1) *Performance requirement.* (i) The labeling of a product intended as a

laundry additive may bear claims for "disinfection" if, when tested by the method in section 91–4(a)(2) Subdivision G of the Registration Guidelines or its equivalent, the product prevents growth of each test microorganism in fabric subcultures or laundry water subcultures.

(ii) The labeling of a product intended as a laundry additive may bear claims for "sanitizing" if, when tested by the method in section 91–4(a)(3) of Subdivision G of the Registration Guidelines or its equivalent, the product causes at least 99.9 percent reduction in numbers of each test microorganism over the control count for both fabric and laundry water.

(2) *Claims.* The labeling of a product recommended as a laundry additive must differentiate between claims to provide non-residual disinfection and to sanitize during the laundry operation (e.g., "disinfects laundry in wash water," "sanitizes laundry in the final rinse water").

(c) *Residual laundry additives*—(1) *Performance requirement.* The labeling of a product intended as a laundry additive may bear residual "self-sanitizing" claims (that can be identified as related to human health) if, when tested by the method in section 91–4(a)(4) of Subdivision G of the Registration Guidelines or its equivalent, the product demonstrates a reduction of at least 99.9 percent in numbers of each test microorganism over the zero-time control and the parallel untreated control.

(2) *Claims.* Claims for residual antimicrobial activity on laundered materials or articles are acceptable only when such materials are likely to become and remain wet (for example, diapers and bed linens of incontinent persons) during normal conditions of use and storage (e.g., "provides self-sanitizing residual activity against pathogenic microorganisms on bed linens in the presence of wet contamination").

**§ 156.355 Fabric and textile products.**

(a) *Carpet sanitizers—performance requirement.* The labeling of a product intended as a carpet treatment may bear claims as a "sanitizer" if, when tested by the method in section 91–4(b) of Subdivision G of the Registration Guidelines or its equivalent, the product demonstrates a 99.9 percent reduction in numbers of test microorganisms over the scrubbed control.

(b) *Mattress and upholstered furniture treatments—performance requirement.* The labeling of a gas or fumigant product intended for treatment of mattresses, upholstered furniture, pillows, and similar objects may bear claims as a "sterilizer," and "disinfectant," or "sanitizer" if, when tested against the criteria in section 91–4(c) of Subdivision G of the Registration Guidelines or its equivalent, the product meets the performance requirement specified:

(1) In § 156.300(a) for sterilizers; or

(2) In § 156.305(a) for disinfectants; or

(3) In § 156.335(a) for sanitizers.

(c) *Fabric impregnating treatments*—(1) *Performance requirement.* The labeling of a product intended for impregnating fabrics may bear residual "self-sanitizing" claims if, when tested by the method in section 91–2(m) of Subdivision G of the Registration Guidelines or its equivalent, the product achieves at least a 99.9 percent reduction in numbers of test microorganisms on the treated fabric(s) over those on the zero-time control and the parallel untreated control.

(2) *Claims.* Claims must be limited to residual self-sanitizing levels of activity in the presence of moisture. Labeling must indicate the duration of effectiveness of the residual activity.

**§ 156.360 Air sanitizers.**

(a) *Performance requirement.* The labeling of a product intended for the treatment of air in enclosed spaces may bear claims as a "sanitizer" if, when tested by the appropriate method in section 91–5 of Subdivision G of the Registration Guidelines or its equivalent, the product meets one of the following standards:

(1) If the product contains glycols, a vapor concentration of 50 percent saturation or more in the air of the test enclosure; or

(2) If the product does not contain glycols, a reduction of at least 99.9 percent of test microorganisms over the parallel untreated control in the air of the test enclosure.

(b) *Claims.* Claims that a product prevents diseases, or provides any other health protection, whether expressed or implied, are not acceptable. Claims must clearly indicate the mitigating nature of the activity, such as "Temporarily reduces the number of airborne bacteria."

**§ 156.365 Toilet bowl and urinal treatments.**

(a) *Surface treatments*—(1) *Performance requirement.* The labeling of a product intended for toilet bowl and urinal surface treatment may bear "disinfecting" or "sanitizing" claims if, when tested by the appropriate method in section 91–2 (b), (c), (d), or (j) of Subdivision G of the Registration Guidelines or its equivalent, the product meets the performance requirement specified in:

(i) Section 156.305(a) for disinfectants; or

(ii) Section 156.335(a) for sanitizers.

(2) *Claims.* Claims for disinfecting or sanitizing toilet bowl and urinal surfaces are acceptable. Claims for disinfecting the hidden trap and claims for solutions in the tank to disinfect or sanitize the bowl surface each time the toilet is flushed are not acceptable.

(b) *Water treatments*—(1) *Performance requirement.* The labeling of a product intended for treating toilet bowl and urinal water may bear "sanitizing" claims (that can be identified as related to human health) if, when tested by the method in section 91–7(b) of Subdivision G of the Registration Guidelines or its equivalent, the product demonstrates at least a 99.9 percent reduction in numbers of test microorganisms over the zero-time control and the parallel untreated control.

(2) *Claims.* Claims for products of this type must either pertain to sanitizing activity or aesthetic benefits commonly associated with control of odor, slime, or other aesthetic problems in toilet and urinal bowl water. Examples of acceptable claims are: "Inhibits the production of ammoniacal odors produced by bacteria in toilet and urinal bowl water," "Controls unsightly slime formation produced by bacteria in toilet and urinal bowl water," and "Sanitizes toilet bowl water." Only sanitizing claims can be identified as related to human health considerations.

**§ 156.370 Human drinking water treatments.**

(a) *Emergency water supplies—performance requirement.* The labeling of a product intended for emergency treatment of drinking water may bear a claim as a "disinfectant" if, when tested by the method in section 91–8(a)(2) of Subdivision G of the Registration Guidelines or its equivalent, the product kills all test microorganisms in the water.

(b) *Water purifier units—performance requirement.* The labeling may bear claims for "purification" of raw water if, when tested by the method in section 91–8(a)(3) of Subdivision G of the Registration Guidelines or its equivalent, the product eliminates the microbial pollution from the water.

**§ 156.375 Swimming pool water treatments.**

The labeling of a product intended for treatment of swimming pool water may bear claims for "disinfection" if, when

tested according to the laboratory and field methods in section 91–8(c)(1) of Subdivision G of the Registration Guidelines or its equivalent, the product meets both of the following criteria:

(a) *Laboratory test.* The product meets or exceeds the performance of the sodium hypochlorite control against each test microorganism.

(b) *Field test.* Not more than 15 percent of the samples collected fail to meet all of the following bacterial indices:

(1) The standard plate count at 35 °C does not exceed 200 colonies per 1.0 ml.

(2) The most probable number of coliform bacteria is less than 2.2 organisms per 100 ml. If the membrane filter test is used, there shall be no more than 1.0 coliform organism per 50 ml.

(3) The most probable number of enterococcal organisms is less than 2.2 organisms per 100 ml. If the membrane filter test is used there shall be no more than 1.0 enterococcal organism per 50 ml.

**§ 156.380 Health-related and non-health-related claims for antimicrobial products.**

The Agency will use the following criteria to determine whether or not the labeling of an antimicrobial agent bears claims of human health significance:

(a) Products bearing labeling claims to control specific microorganisms infectious for man, such as *Staphylococcus aureous, Mycobacterium tuberculosis,* sand *Pseudomonas aeruginosa,* are considered to be directly related to human health.

(b) All sterilizers, hospital disinfectants, swimming pool water disinfectants, human drinking water disinfectants and purifiers, and food-contact surface sanitizers are human health-related, whether or not control if infectious microorganisms is specifically claimed.

(c) Veterinary and animal premise disinfectants are considered human health-related if microorganisms that are infectious for both man and animals are involved, such as *Staphylococcus aureus* and *Pseudomonas aeruginosa.* Microorganisms that are solely pathogenic for animals (such as canine distemper virus and hog cholera virus) are not considered human health-related.

(d) Claims for products as disinfectants or sanitizers are considered to include or imply effectiveness against microorganisms infectious for man. Such claims must be expressly qualified (e.g., "odor-causing bacteria" or "slime-forming bacteria") in order to remove implications of human health significance. In addition, if the intent of the claim is not clearly defined, a labeling disclosure of ineffectiveness of the product against health-related micro-organisms may be required (e.g., "This product has not been demonstrated to be effective against microorganisms infectious for man").

(e) Since elimination or significant reduction in numbers of microorganisms (sterilization, disinfection, sanitization) must be demonstrated before a product is considered acceptable for claims against microorganisms infectious for humans, or for use in medical or sickroom environments, products bearing claims for effectiveness at the bacteriostatic (inhibition of growth) level are not acceptable for such uses. Bacteriostatic claims are acceptable only for products expressly recommended for control of microorganisms of only economic or aesthetic significance, e.g., spoilage bacteria and ordor-causing bacteria.

(f) Slime and ordor control agents, preservatives, algicides, and other products expressly claiming control of microorganisms of economic or aesthetic significance are not considered to be human health-related, but are nevertheless subject to the requirements for accurate label claims and adequate directions for a practical pattern of use.

## PART 167—REGISTRATION OF PESTICIDE PRODUCING ESTABLISHMENTS AND SUBMISSION OF PESTICIDES REPORTS

2.a. By revising the heading of Part 167 to read as set forth above.

**§ 167.4 [Removed]**

b. By removing § 167.4

(Sec. 2, 3, 5, 6, 7, 9, 10, 12, 17, 19, and 25 of the Federal Insecticide, Fungecide, and Rodenticide Act, as amended, 7 U.S.C. 136–136y)

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Part IV

# Environmental Protection Agency

40 CFR Parts 122, 124, and 125
National Pollutant Discharge Elimination System Permit Regulations; Final Rule

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 122, 124, and 125**

**[OW-FRL-2532-8]**

## National Pollutant Discharge Elimination System Permit Regulations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** On May 19, 1980, the Environmental Protection Agency published final rules which consolidated the regulations and procedures for five EPA permit programs including the National Pollutant Discharge Elimination System (NPDES) permit program under section 402 of the Clean Water Act (CWA). Following promulgation of these Consolidated Permit Regulations, petitions for review of various aspects of these regulations were filed in several federal courts and were subsequently consolidated into a single action in the United States Court of Appeals for the District of Columbia Circuit (*NRDC* v. *EPA*, and consolidated cases, No. 80–1607 (D.C. Cir., filed June 2, 1980)). On June 7, 1982, EPA entered into a settlement agreement on Clean Water Act issues with numerous industry petitioners. Under the terms of that settlement, EPA agreed to propose changes to the May 19, 1980 regulations to reflect the resolution of issues in the settlement. EPA also agreed to take such action as may be necessary to suspend several sections of the regulations pending completion of final rulemaking. Accordingly, EPA proposed amendments to the NPDES sections of the Consolidated Permit Regulations on November 18, 1982. At the same time, EPA proposed to suspend portions of these regulations and related provisions of the NPDES application forms to correspond with proposed changes to the regulation agreed to in that settlement.

After considering numerous comments submitted on the proposed changes, EPA has developed the amended NPDES regulations which are promulgated in final form today. Today's action also represents the final rulemaking on the proposed suspensions. No final action had been taken previously since the most expeditious manner of resolving all outstanding issues was to complete rulemaking on the suspension issues as well as the others at the same time.

Today's rulemaking also contains final regulations for determining whether a facility is a new source. EPA suspended the existing new source criteria and proposed revisions to these regulations on September 9, 1980 (40 FR 59317).

**DATES:** The effective date of this regulation is October 26, 1984.

In accordance with 40 CFR 100.01 (45 FR 26098, April 17, 1980), these regulations shall be considered final agency action for purposes of judicial review at 1:00 p.m. eastern time on October 10, 1984. In order to assist EPA to correct any typographical errors, incorrect cross references, and similar technical errors, comments of a technical and nonsubstantive nature on the final regulations may be submitted on or before November 26, 1984. The effective date of these regulations will not be delayed by consideration of such comments.

The modified information requirements contained in §§ 122.29(c)(5), 122.41(l)(1), 122.42(a), 122.45(b), 122.62(a), and 124.5 have not been approved by the Office of Management and Budget (OMB) and they are not effective until OMB has approved them.

**ADDRESS:** Comments of a technical and nonsubstantive nature should be addressed to: William Diamond, Permit Division (EN–336), Office of Water Enforcement and Permits, U.S. Environmental Protection Agency, Washington, D.C. 20460.

**FOR FURTHER INFORMATION CONTACT:** William Diamond, Permits Division (EN–336), Office of Water Enforcement and Permits, U.S. Environmental Protection Agency, Washington, D.C. 20460. Telephone: (202) 426–4793.

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## I. BACKGROUND

On June 7, 1979, EPA published final regulations establishing program requirements and procedures for the NPDES program. A week later, on June 14, 1979, a number of petitioners representing major industrial trade associations, several of their member companies, the Natural Resources Defense Council (NRDC), and Citizens for a Better Environment filed petitions for judicial review of the regulations. Also on June 14, 1979, EPA published proposed regulations consolidating the requirements and procedures for five EPA permit programs. These included the NPDES program under the Clean Water Act (CWA), the Underground Injection Control (UIC) program under the Safe Drinking Water Act (SDWA), State "dredge or fill" programs under Section 404 of the CWA, the Hazardous Waste Management (HWM) program under the Resource Conservation and Recovery Act (RCRA), and the Prevention of Significant Deterioration (PSD) program under the Clean Air Act.

Final Consolidated Permit Regulations (CPR) were published on May 19, 1980. These consolidated regulations were challenged in court. Petitions for review were filed in several U.S. Courts of Appeal and subsequently consolidated in the District of Columbia Circuit (*NRDC* v. *EPA*, and consolidated cases [No. 80–1607, filed June 2, 1980]). The petitions for review of the final NPDES regulations published June 7, 1979, were joined with this action. In response to these challenges, on September 9, 1980 EPA suspended the criteria for

determining whether a discharge is a new source (40 FR 59317). On the same day, EPA proposed regulations to replace the new source criteria (45 FR 59343).

EPA held extensive discussions with all litigants on the remaining issues raised in the petitions and subsequently signed four separate settlement agreements with the industry parties. One agreement covered only the UIC program, one covered the HWM program under RCRA, one covered the NPDES program, and the fourth covered issues which were common to at least two of the three permit programs involved in the litigation along with the definition of "new discharger" and its relationship to mobile drilling rigs under the NPDES program. Today's final rulemaking completes action initiated as a result of the settlement of NPDES issues.

The NPDES Settlement Agreement was reached after two years of intensive negotiations between EPA and the industry groups challenging the regulations. Industry litigants had raised approximately 47 issues affecting both substantive and procedural requirements in the NPDES regulations.

EPA signed the NPDES Settlement Agreement with industry petitioners on June 7, 1982. The settlement covered 27 of the 47 issues raised by industry litigants challenging the NPDES permitting portions of the Agency's regulations. Nine other issues were covered under the Common Issues Settlement Agreement. Of the nine, three related specifically to the NPDES permit program while the remaining six covered generic requirements common to all EPA permit programs. The remaining issues were determined either to be inappropriate for review except in the context of individual permit issuance or not capable of resolution among the parties. Additionally, no resolution was reached on other issues raised by the environmental group petitioners.

Under the terms of the NPDES Settlement Agreement, EPA agreed to propose revisions to the NPDES regulations. EPA also agreed to include certain language in the preamble to the proposed revisions that reflected the intent of the agreement. Finally, EPA agreed to take action necessary to suspend certain provisions, primarily relating to permit application requirements. The parties to the settlement agreed to withdraw their challenges to the regulations to the extent EPA promulgates final regulations and preamble language substantially the same as and not altering the meaning of the language agreed to in the settlement agreement.

EPA received comments from many interested persons, including some of the parties to the settlement agreement, requesting that the rules be changed in ways different from those set forth in the agreement. EPA has considered carefully all such comments and has made changes in response to these.

On those issues in which final action differs from that proposed, industry litigants may decide to continue their challenges in court. Petitioners, the Natural Resources Defense council and Citizens for a Better Environment, are not parties to the settlement agreement. Their challenges to provisions of the reagulations may not be withdrawn as a result of today's final promulgation of changes to parts of the regulations. Certain industrial petitioners have also indicated an intention to litigate certain NPDES issues raised in their petitions that were not resolved by the settlement agreement and not covered by the proposed rules. In addition, two of the industry parties (Mobil Oil Company and the American Iron and Steel Institute (AISI)) did not join in the settlement of the net/gross issue (40 CFR 122.45(h) [CPR 122.63(h)]) and AISI did not join in the settlement of the total metals issue (40 CFR 122.45(c) [CPR 122.63(c)]). (See discussion below of citing format.)

EPA published proposed rules implementing the settlement agreement on November 18, 1982 (47 FR 52072). At the same time, proposed suspensions were also published (47 FR 52093). The comment period for the proposed rule closed on January 17, 1983. EPA received approximately 85 comments from numerous industries and trade associations, eight States and four environmental groups. Most of these comments were concentrated on a few issues such as the toxics control strategy, storm water discharges, anti-backsliding, and the construction prohibition for new sources.

The proposed changes in the regulations resulted from the settlement of challenges under the CWA to provisions of the regulations affecting the NPDES program. However, some of the changes to Part 124 affect RCRA, PSD, and UIC programs as well. EPA solicited comments on the extent to which the November 18, 1982 proposed changes to these sections should affect RCRA, PSD, and UIC permitting. No comments were received on this issue. Today's rulemaking implements several procedural changes to Part 124, Procedures for Decision-making, which minimally affect the RCRA, PSD, and UIC permit programs.

On April 1, 1983, EPA published final rules "deconsolidating" the Consolidated Permit Regulations (48 FR 14146 [April 1, 1983]). The rule was published as a technical amendment to the regulations, and resulted in no substantive revisions. Under the deconsolidation, the permit regulations for each of the five programs appear in different portions to Chapter 40 of the Code of Federal Regulations. The NPDES regulations remain in Parts 122 and 123 (Part 124 was not affected by the revision and still applies to all of the programs). The deconsolidation of the NPDES regulations resulted in a renumbering of the provisions in Parts 122 and 123. Since the November 18, 1982 proposed regulations were published as revisions to the Consolidated Permit Regulations and the April 1 revisions completely renumbered the NPDES portions of the Consolidated Permit Regulations in Part 122, the format used in this preamble generally includes the Consolidated Permit Regulations (CPR) citation in brackets following the new (April 1) NPDES citation. For example: § 122.21 [CPR § 122.53]. This approach should help to eliminate confusion.

Today's final regulations reflect a final Agency determination on the proposed changes after full consideration of the comments received. To facilitate understanding, the rulemaking package includes in Part II of this preamble ("Final Regulations") for each part of the regulation EPA proposed to change a detailed discussion of the original regulation, the November 18, 1982 proposed change, the reasons for the proposal, the Agency's response to comments, and the final Agency determination.

Today's action also revises the portion of the NPDES regulations establishing criteria for new sources. As stated above, as a result of the challenge to the Consolidated Permit Regulations, EPA suspended the new source criteria (45 FR 59317) in the regulations and proposed substitute criteria. Because the revision to the new source criteria was initiated as a result of the challenge to the regulations, we have included the final action in this rulemaking.

For certain issues, today's final action is identical to the November 18, 1982, proposal, and thus consistent with the NPDES Settlement Agreement. However, some of the proposed rules have been modified, in some cases to retain existing regulatory requirements, as a result of EPA's review of the issues

and the public comments received on the proposal.

The implementation of the changes made to the NPDES permit program as a result of today's rulemaking affects one of the permit application forms (Form 2c). To assist the public in understanding these changes, EPA is publishing the revised Form 2c along with this rulemaking. However, because many States and EPA regional offices have large supplies of existing Form 2c, it is both administratively and economically impractical to immediately convert to the new permit application form. Therefore, the old permit application Form 2c will continue to be used until all have been used up and/or until copies of the revised Form 2c permit application can be furnished to the States and EPA regional offices. Since permit applicants must comply with the changes in the NPDES permit program resulting from today's rulemaking, applicants should cross out the sections of the existing Form 2c which no longer apply and insert the new information required. States and EPA regional offices may wish to prepare an addendum to the permit application Form 2c which explains the changes in reporting requirements.

## II. FINAL REGULATIONS

### A. Toxics Control Strategy (40 CFR 122.21 [CPR § 122.53], 122.42 [CPR § 122.61], 122.44 [CPR § 122.62], 122.62 [CPR § 122.15])

The Agency proposed a number of changes to regulatory provisions that are part of the Agency's overall strategy for controlling toxic pollutant discharges under the NPDES program. EPA previously discussed its Toxic Control Strategy in issuing the final Consolidated Application Forms (45 FR 33516, May 19, 1980). The NPDES effort to regulate the discharge of toxic pollutants is extensive. To assist readers in understanding how the proposed revisions and today's final rule fit into this strategy, it is appropriate to provide the public with a statement of the NPDES Toxic Control Strategy. Before discussing the changes to the regulations, today's preamble will outline some of the major objectives of the strategy.

*(1) Background*

Congress established the basis for controlling toxic discharges in the Federal Water Pollution Control Act Amendments of 1972 (FWPCA). Section 307(a) of the FWPCA required EPA to develop a list of toxic pollutants for which the Agency would establish effluent standards. These standards (or discharge prohibitions) were to be established on a pollutant-by-pollutant basis within 180 days of listing as a toxic pollutant. EPA has established section 307(a) standards for only six toxic pollutants since 1972.

Concerned about the Agency's perceived lack of emphasis on controlling toxic pollutants and lack of progress in establishing section 307(a) standards, the Natural Resources Defense Council (NRDC) file suit. The parties entered into a Consent Decree which subsequently formed the basis for the Agency's regulation of toxics. *NRDC v. EPA*, 8 E.R.C. 2110 (D.D.C. 1976). Under the Consent Decree, EPA would supplement the 307(a) standard approach with regulation of pollutant discharges, including toxics, through effluent limitation guidelines promulgated for industrial categories or subcategories. EPA was to establish effluent limitation guidelines reflecting the Best Available Technology Economically Achievable (BAT) to control a list of 65 classes of toxic pollutants in each of 21 primary industrial categories defined in the Consent Decree (the 65 classes were subsequently expanded to 129 toxic pollutants and the 21 industry categories were further subdivided into 34 categories). Congress, in the 1977 Clean Water Act Amendments, adopted the Consent Decree approach towards controlling toxic pollutant discharges.

In August 1978, EPA proposed NPDES regulations to implement the requirements of the Consent Decree and the 1977 CWA amendments. These regulations, published as final NPDES regulations on June 7, 1979, for the first time focused on obtaining adequate information on toxic pollutants through the permit application process. The final Consolidated Permit Regulations promulgated May 19, 1980, retained the NPDES provisions relating to the control of toxic pollutants.

The Agency's NPDES Toxic Control Strategy, which was discussed in detail in the preamble to the Consolidated Permit Application Forms, consists of three central elements.

First, the agency established a comprehensive process for identifying, reporting the presence of and gathering data on toxic pollutants in discharges. In addition to EPA's effluent limitation guideline effort, this activity is implemented through the NPDES permit application requirements. Permit applicants are required to identify the presence of toxic pollutants, and in certain circumstances, must submit data indicating the quantities and concentrations of pollutants present. To ensure that the data accurately describe the discharge, sampling methods and minimum sampling requirements are also specified.

The second element of the Toxic Control Strategy is to establish specific effluent limitations in NPDES permits. Permit limitations are generally based either upon promulgated effluent limitation guidelines (technology-based limits) or State water quality standards (water quality-based limits). In the absence of or in combination with a promulgated guideline, EPA establishes technology-based limitations on a case-by-case basis under section 402(a)(1) of the CWA based on the permit writer's best professional judgment. EPA establishes permit effluent limitations on individual toxic pollutants or "indicator" pollutants that will assure adequate treatment of toxics (e.g. COD, TSS, TOC, etc.). Where these are inadequate, permit limitations may be established in terms of effluent toxicity.

The third element of the strategy is to ensure that the permitting authority receives adequate information concerning the discharge during the term of the permit and has the ability to adjust the permit if necessary. All permits require dischargers to monitor their effluent for pollutants (including toxic pollutants) limited in the permit and to report the results. These reports enable the permitting authority to determine compliance by the permittee. In addition, permittees generally must provide notice of new or potential discharges of toxic pollutants. The Director can then decide whether a change in the permit is necessary to control the modified discharge. The regulations specify the circumstances under which permits can be modified.

EPA has authority to request additional information to supplement permit applications or later compliance monitoring reports where necessary to carry out the objectives of the Act.

The regulations implementing the Toxic Control Strategy reflect a balance between the need for adequate information to control the discharge of toxic pollutants and the burden these requirements impose on the regulated public. The existing rules represent the Agency's initial decision on the appropriate balance. Litigants sued EPA because they disagreed with that decision. The November 18, 1982 proposal allowed the Agency to solicit public comment on possible changes to the existing rule. Today's final rule represents EPA's decision on what is necessary to provide adequate environmental protection yet not unduly burdensome or unproductive. EPA has

adopted some of the litigation settlement proposals as final rules. The changes adopted today will not inhibit the Agency's ability to carry out any of the elements in its Toxic Control Strategy.

*(2) Quantitative Data Requirements (40 CFR 122.21(g)(7) [CPR § 122.53(d)(7)])*

EPA's strategy for gathering specific information on toxic pollutants in existing industrial discharges relies primarily upon application Form 2c. Most important, the application requires disclosure of the presence and, for some pollutants, the quantities of specified pollutants in the discharge.

EPA proposed several changes to the quantitative data requirements of the application form. A brief overview of all the application data requirements will put these changes in perspective.

*All* applicants must test for and report quantitative data for seven listed conventional and nonconventional pollutants (§ 122.21(g)(7)(i) and Item V–A in Form 2c). The Director may waive testing for any or all of these pollutants for individual dischargers in certain circumstances.

In addition, all applicants must provide information on the presence of toxic pollutants in accordance with a scheme set forth in the regulation. In established testing requirements for toxic pollutants (metals and organic chemicals, with the addition of cyanide and total phenols), EPA balances the likelihood of the presence of the pollutants against the costs and burdens for applicants to analyze the effluent. It is unnecessary to require all applicants to test for all pollutants. In some industries there is no reasonable expectation that certain pollutants are present. Therefore, mandatory testing for any toxic pollutants applies only where EPA data (gathered primarily through the effluent guidelines development process) have indicated a likelihood that the pollutant will be present in the discharge. Testing requirements for toxic pollutants fall into two groups.

First, all process discharges in primary industrial categories must be tested for the presence of metals, cyanide and total phenols (§ 122.21(g)(7))(ii) and Item V–C of Form 2c.) However, testing is not required for all organic toxic pollutants in all primary industry categories. The specific organic pollutants for which an industy must test are listed in the regulations according to the fractions tested by the analytical procedure which uses gas chromatography/mass spectrometry (GC/MS). For example, organic chemical facilities are required to analyze for all fractions, while coal mining operations are not required to test for any organic chemicals by this provision of the regulations.

Second, in addition to the mandatory testing explained above, *all* industrial dischargers must report quantitative data for any toxic pollutant that they know or have reason to believe is present in the discharge. A similar requirement applies to certain listed conventional pollutants, twenty-one nonconventional pollutants, and radioactivity. (§ 122.21(g)(7)(iii)(B) and Item V–B of Form 2c).

In addition to the toxic pollutant testing explained above, each applicant must indicate whether it knows or has reason to believe that certain hazardous substances or asbestos are discharged, and briefly explain why. Each applicant must also identify the presence of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) if it uses or manufactures certain listed substances or expects TCDD to be in its discharge.

(a) Mandatory Testing

*1. Existing rules.* As mentioned above, the NPDES regulations require all applicants to submit quantitative data for three conventional pollutants (BOD, Total Suspended Solids, and pH) and four nonconventional pollutants (Chemical Oxygen Demand, Total Organic Carbon, Ammonia, and Temperature). (§ 122.21(g)(7)(i) and Item V–A of Form 2c). Testing is required since these pollutants are commonly found in many different types of discharges and tend to be indicative of the nature of a discharge. Applicants may request the Director to waive this requirement for one or more of the pollutants. As discussed, there is also mandatory testing for toxic metals and organic pollutants required for process discharges from primary industrial categories (§ 122.21(g)(7)(ii)), but changes were not proposed to these provisions.

*2. Proposed changes.* EPA proposed to clarify the provision allowing the Director to waive the testing requirement for the seven listed conventional and nonconventional pollutants. The proposal stated that in order to obtain the waiver, the applicant must demonstrate that the reduced reporting will still provide the Director with sufficient information to write adequate permit limitations. Additionally, the proposal would make it clear that requests for waivers could be submitted not only for individual facilities, but also for an entire industry category or subcategory. Waiver requests for an entire category or subcategory of discharges should be submitted to the Director, Office of Water Enforcement and Permits.

*3. Comments and responses.* EPA received no comments on this proposal.

*4. EPA action.* The final rule clarifying the waiver provision is adopted as proposed.

(b) Testing Potentially Required—Toxic Pollutants

*1. Existing regulations.* All permit applicants must report quantitative data on any listed toxic pollutant and certain conventional and nonconventional pollutants the discharger knows or has reason to believe are present in the discharge (§ 122.21(g)(7)(iii)(A) and (B) [CPR § 122.53(d)(7)(iii)]; Items V–B and V–C of Form 2c). This testing is in addition to the mandatory testing for toxic pollutants of process discharges in primary industry categories. Testing requirements for toxic pollutants are established to ensure that permitting authorities receive adequate information on the presence of toxic pollutants in a discharge. This information enables permit writers to establish appropriate limitations to control pollutants that may be of concern. Permitting authorities are not required to establish effluent limitations for all toxic pollutants on which a discharger reports quantitative data under the "know or have reason to believe" standard. In general, EPA does not intend that information supplied in the application process automatically trigger the establishment of effluent limitations. Rather, it allows the permit writer to make appropriate judgments about the need for such limitations. The regulations require the establishment of permit limitations if the pollutants are or may be discharged above the technology-based levels applicable to the discharge (as specified in effluent limitations guidelines or developed through the permit writer's best professional judgment) or, before today's revision, if they are used or manufactured at the permitted facility (see Part A. (5), below).

*2. Proposed changes.* Industry litigants were concerned that the toxic pollutant testing requirements were too extensive. They felt the regulation was unclear on how applicants should determine whether pollutants are "believed to be present" and that it failed to address *de minimis* quantities of pollutants. Industry contended the "believed to be present" provision required them to test, unnecessarily, for *all* pollutants that could be present in any amounts, simply to assure that the applicant would not be liable for incomplete and false reporting. In response to these concerns,

EPA proposed to establish a threshold level below which testing would not be required. Applicants would be required to submit quantitative data only for those toxic pollutants that they know or have reason to believe are present in the discharge at levels exceeding 100 μg/1 (parts per billion (ppb)). For four pollutants (acrolein, acrylonitrile, 2,4-dinitrophenol, and 2-methyl-,4,6-dinitrophenol), EPA proposed a higher threshold of 500 ppb. If an applicant knew or believed a toxic pollutant was present at less than the threshold level, the applicant could either submit quantitative data or simply explain why the applicant thought it was in the discharge. As noted in the preamble, and reflected in the proposed regulation, this cut-off would not apply to testing for process discharges in the primary industry categories.

The threshold levels in the proposal were seen as a compromise between industry's desire for a level that would eliminate testing for pollutant discharges in extremely small amounts and concentrations and EPA's need to have sufficient data to identify the presence of pollutants which should be controlled through permit limitations. This is particularly important because in accordance with section 402(k) of the CWA, a permittee is deemed to be in compliance with the CWA if he meets the requirements and limitations of his permit. Thus, pollutants not prohibited or limited by the permit can be discharged unless and until the permit is modified. EPA acknowledged in the preamble that EPA water quality criteria indicate that many of the pollutants required to be analyzed are known to cause significant adverse impact to aquatic organisms and human health at levels of 100 ppb or less (47 FR 52075, November 18, 1982).

EPA also based the 100 ppb upon an assessment of GC/MS methods 624 and 625 (as proposed December 3, 1979, 44 FR 69464). In general, those methods indicated a detection limit of 10 ppb or less for most toxic pollutants. For purposes of the application proposal, EPA then multiplied those limits by a factor of 10 as a rough measure to respond to concerns about analytical variability. EPA described this variability factor as "conservative," based upon Agency analytical experience. The higher threshold for four specific toxic pollutants was based upon the same proposed test methods, although a smaller variability factor was added since there is far less analytical variability at higher concentrations.

The proposal was intended primarily to minimize analytical burdens on applicants, while still providing permit writers with adequate information to evaluate a discharge and write appropriate effluent limitations. EPA's concern about the suitability of this proposed revision led the Agency to specifically request in the preamble that the public comment on the appropriateness of establishing threshold levels and whether 100 ppb was a reasonable level.

*3. Comments and responses.* This provision generated a great deal of comment. Several commenters opposed the 100 ppb threshold level. Several States that have been administering the NPDES program commented that threshold levels were inappropriate and applicants should submit quantitative data for any toxic pollutant they know or have reason to believe is present in the discharge in any amount. They felt that extensive application data on toxic pollutants are essential to any effective toxic pollutant control program and that the cost of testing is not excessive relative to the information gained. Several pointed to statements in EPA's own preamble that many pollutants are toxic below 100 ppb. One State commenter suggested that applicants should be required to submit quantitative data unless the Director specifically waives the requirement for an individual facility. Industry commenters supported the threshold concept. They suggested that it should be extended to other requirements and that the testing threshold should be raised to 250 ppb, or even higher. They argued that the analytical variability of samples taken at low concentrations resulted in imprecise date which should not be used in establishing permit effluent limitations.

After careful review of the comments and of the possible impacts of a 100 ppb threshold, we have concluded that the proposed threshold was too high. Requiring applicants to submit quantitative data on any pollutant that they know or have reason to believe is present in the discharge will supply permit writers with information that is often necessary in developing appropriate permit conditions, including monitoring and reporting requirements. This is consistent with the purpose of the application to provide permitting authorities with sufficient information to fully evaluate the discharge. Permitting authorities can use the data to identify pollutants that may be of concern and in appropriate cases, to control them through effluent limitations in the permit.

The Agency recognizes that quantitative data at extremely low levels may have some uncertainties, although those uncertainties are more likely to concern accuracy of specific *quantitative* readings than to involve any false positive readings of pollutants that actually are not present. Nonetheless, even at levels where the accuracy of the data may be somewhat uncertain, analytical information is useful to the permitting authority as a screening technique to identify the presence of a pollutant and supply an estimate of its concentration. Permit writers will be aware of any uncertainty as to the accuracy of the data submitted on the application. If more precise information is necessary to set permit limitations, the permit writer can request additional quantitative data through a gas chromatography (GC) test tailored to a specific pollutant. These GC test methods provide more accurate data at much lower levels than the GC/MS test methods which dischargers will generally use and at much less cost.

Industry's concern that there is a level below which quantitative data are of little value does have some legitimacy; but it is most significant only at levels low enough to trigger some likelihood of "false positives." Therefore, EPA has decided to retain the threshold concept, but to set it at a level where the data are sufficiently accurate to be useful and the value of the data is not outweighed by the burden of testing imposed on the applicant. After the review of the available information, the Agency has decided that a threshold of 10 ppb best achieves this balance.

There are several reasons why the Agency is establishing this new threshold level. As several commenters observed, a number of toxic pollutants are acutely toxic at levels below 100 ppb. EPA water quality criteria indicate that many of the organic toxic pollutants (e.g. chlordane, aldrin) are either carcinogenic or acutely toxic at levels well below 100 ppb (in a number of cases, toxic effects occur below both GC and GC/MS detection limits). The criteria also indicate that many of the toxic metals have effects at levels near or below 10 ppb (e.g., cadmium, hexavalent chromium). Under the proposal, permit writer would only be able to obtain data on these toxic pollutants if the permittee expected discharge at or above 100 ppb, well in excess of the levels where health or aquatic effects occur. Several States approved to administer the NPDES program commented that given these toxicity levels, it is important to require a submission of data at lower levels. On reconsideration, EPA agrees that data on these toxic pollutants at low levels

may be necessary for comprehensive evaluation of a discharge and establishment of permit limits.

The proposed threshold level was designed to take into account the possibility of imprecision and analytical variability associated with testing for toxic pollutants at levels near detection limits. EPA based the proposed threshold on method detection limits for the proposed GC/MS methods 624 and 625 (see 44 FR 69464, December 3, 1979), since multi-pollutant GC/MS testing will generally be used to report quantitative data on toxic pollutants. To take into account analytical variability, EPA added a variability factor of ten to the general detection limit of 10 ppb, which resulted in a proposed threshold of 100 ppb (for 4 pollutants with higher detection limits, a lower variability factor was set, resulting in a 500 ppb threshold).

The final rule contains an application testing threshold at 10 ppb, based in large part upon the detection limits in the proposed GC/MS test methods (see above), without the addition of the variability factor of ten. The proposed methods indicate that most organic toxic pollutants can be detected in waste water at that level (see 44 FR 69532, December 3, 1979). (For the four toxic pollutants discussed above that cannot be detected at 10 ppb the Agency is establishing a higher threshold at 100 ppb.) EPA recognizes that the 10 ppb threshold is based upon proposed methods rather than final rules. However, since the testing threshold is intended as a general number for testing purposes, the proposal is sufficiently accurate as a basis for the threshold. Moreover, more recent Agency data on these test methods confirm these detection limits and, in fact, indicate that GC/MS detection limits are actually lower.

The final rule is based upon a determination that it is unnecessary to include a variability factor above the detection limit in the testing threshold. While such a factor may be appropriate in some cases, such as in the establishment of effluent limitations since compliance is based upon these limits, a similar degree of precision is not necessary in establishing a testing threshold for permit applications, particularly since the data often serve a screening function. In fact, variability factors incorporated into the application threshold deprive permit writers of valuable information. The application is intended to obtain complete information on the discharge, thus enabling permit writers to determine the parameters for which permit limits must be set. This can be accomplished even if the initial data are somewhat imprecise due to alleged analytical variability since the permit writer will still have enough information to evaluate the discharge and can take such factors into account at the time of establishing permit limitations. If more precise data are needed to establish permit limitations at levels where variability may be a concern, the permittee is free to submit such data and the permit writer retains the authority to request additional data on the toxics, such as through more accurate GC testing.

Furthermore, in developing method detection limits, EPA has already considered analytical variability to some degree. Thus, adding a variability factor of ten to the detection limits compounds the consideration of analytical variability. In light of concerns expressed by commenters that the 100 ppb threshold would deprive permit writers of application data necessary to fully evaluate a discharge, it is not appropriate to add this second variability factor.

The Agency has also determined in rulemaking published subsequent to the November 18, 1982 proposal, that not only detection, but quantification of toxic pollutants below 100 ppb is possible, thus further confirming EPA's reliance on the 10 ppb figure. The proposed effluent limitations guideline for the Organic Chemicals Manufacturing Point Source Category contains limitations for a number of organic chemicals at the 50 ppb level (48 FR 11828, March 21, 1983). Moreover, as stated in the preamble to that proposal, EPA recognizes that with careful analytical techniques, toxic pollutants can be quantified below the levels at which limits were proposed (48 FR 11839). The limitations on the discharge of Total Toxic Organic (TTO) pollutants in the final Effluent Guidelines for the Electroplating and Metal Finishing Point Source Categories are based upon adding all quantifiable values of the 113 toxic organic pollutants over 10 ppb to determine whether the discharge complies with the TTO limitations. (48 FR 32462, July 15, 1983.) For most of the organic toxic pollutants, the Final Development Document for the Metal Finishing effluent guideline indicates that 10 ppb is an appropriate quantification level. EPA also proposed limitations for one toxic pollutant, N-nitrosodi-n-propylamine, at one ppb and numerous other toxic pollutants at levels between 20 and 50 ppb in the Pesticide Chemicals Guideline (47 FR 53994, November 30, 1982). The Agency recently made available for comment data on the Pesticides Category that would set limitations on a number of pollutants in the 10 ppb to 20 ppb range (49 FR 24492, June 13, 1984).

For four toxic pollutants (acrolein, acrylonitrite, 2,4-dinitrophenol, and 2-methyl-4,6-dinitrophenol), EPA is establishing a higher application testing threshold of 100 ppb (EPA had proposed 500 ppb). The proposed GC/MS test methods indicate that two of these pollutants are detectable at 100 ppb and the others (the phenolic compounds) at 250 ppb. However, the same proposal indicated that both of the phenolic compounds were detectable using GC methods at levels well below 100 ppb (44 FR 69487, December 3, 1979). Thus if applicants expect concentration below the GC/MS detection limit, they can perform GC analysis to obtain the precise data.

Finally, while analytical variability may be higher for samples taken at extremely low concentrations, it is not necessary or appropriate to eliminate all uncertainties by setting a relatively high concentration as the threshold. Since the establishment of too high a threshold could trigger a large number of supplemental requests for information to be submitted to the permit writer, this could substantially delay permit issuance and create significant additional burden on both applicants and permit writers. EPA concluded that it would be appropriate and desirable to set a threshold that will enable permitting authorities in most cases to rely on data submitted from applicants without extensive supplemental information requests.

The threshold level does not mean that permit limitations should necessarily be set for all pollutants present at 10 ppb, nor that it may never be appropriate to set limitations below this level. The submission of data, whether under § 122.21 (g)(7)(iii), (g)(7)(ii) [CPR § 122.53(d)(7) (iii), (ii) (for specified GC/MS fractions), or otherwise, does not automatically trigger the establishment of effluent limitations for the pollutants reported. Before setting technology-based limitations on pollutants present in the discharger's effluent at any level, the permit writer must consider whether the appropriate technology can reduce the pollutants in question to that level, and whether the analytical uncertainty and variability that may exist are so significant that the imposition and enforcement of specific limitations at that level may be unreasonable.

Clearly, for the reasons set forth above, the 250 ppb threshold proposed by some commenters is too high.

One commenter submitted data concerning the fact that analytical variability may be a problem even at 100 ppb. The Agency recognizes that analytical variability is more likely at lower levels. However, as discussed above, EPA does not consider it appropriate to add a variability to the threshold for *application* purposes.

Commenters also questioned EPA's proposal to require toxics testing under the "know or have reason to believe" standard only for routine or frequent discharges. On reconsideration, EPA is persuaded that all toxic pollutant discharges should be tested under the "know or have reason to believe" standard, not just those discharged on a routine or frequent basis. As stated above, the application is intended to provide a complete picture of the permitted facility once every five years. For permit writers fully to evaluate the discharge and impose appropriate permit controls, complete information on the discharge is essential. Even if permit effluent limitations are inappropriate due to the non-routine nature of the discharge, permit writers could determine that control through Best Management Practices (BMP) requirements are necessary or that additional monitoring is warranted. Therefore, the final regulation will apply to all toxic pollutant discharges and eliminate the proposed limitation for only routine or frequent discharges.

One State commenter expressed concern that the 100 ppb application testing threshold would require permit writers to impose additional monitoring requirements to verify the quantities of pollutants reported as being discharged below the threshold. EPA believes that the lower threshold adopted in today's final rules lessens any need to require permit monitoring to verify application information. EPA recognizes, of course, that some State permitting authorities may require pre-application testing for all pollutants the discharger may know or have reason to believe are present. States have the authority to adopt this approach or to request additional data on any pollutant identified in the application and to impose additional monitoring requirements during the permit term.

Another commenter stated that the proposed application testing threshold would interfere with the imposition and enforceability of effluent limitations below the threshold. This concern is also applicable to the lower threshold adopted today. EPA emphasizes that the application testing threshold is established only for triggering a requirement to test for particular toxic pollutants in the application process and it in no way restricts the levels at which effluent limitations can be set for specific pollutants in the permit. Most pollutants can be detected and quantified accurately at the 10 ppb using GC/MS for multi-pollutant analyses. Pure GC methods for a single pollutant frequently are quantifiable well below this level. Determining appropriate effluent limitations involves considering treatment technology as well as possible analytical variabilities when testing a pollutant. Effluent guidelines are developed based on analysis of the treatment capabilities for an industry category. Permit limitations often will be set at levels different from the application testing threshold.

One commenter questioned the basis on which applicants would determine whether a pollutant was likely to be present above the threshold level without testing. Under the regulation, each discharger must assess the likelihood that a particular toxic pollutant will be discharged above the threshold levels. Applicants may base their assessments on available information on the discharge, including their own experience and knowledge. In some cases, applicants can rely upon previous monitoring data for the pollutant, while in others, new testing may be necessary. EPA expects the applicants to consider, among other things, the age and amount of available data, the levels measured in the past, and any changed circumstances that would suggest the need for additional testing. Of course, the permit writer can always request testing for pollutants if he determines it is necessary to evaluate the discharge.

Several commenters stated that the proposed 100 ppb threshold should be applicable to the mandatory testing requirements for process discharges in primary industries as well as testing under the "know or have reason to believe" standard. As discussed above, § 122.21(g)(7)(ii) [CPR § 122.53(d)(7)(ii)] imposes a mandatory duty on applicants in primary industrial categories to test for the presence of certain toxic pollutants as specified in the regulation. The commenters stated that EPA's rationale, that 100 ppb was a technically achievable measurement level using "conservative" variability factors, was also applicable to these discharges.

The mandatory testing requirements for each primary industry category are based upon a review of data on the likelihood that a particular pollutant will be discharged, rather than the more speculative "know or have reason to believe" standard. Because of this difference, an application testing threshold is inappropriate. EPA, in developing effluent limitations guidelines, conducted extensive sampling of primary industries and this information was used in developing the mandatory testing requirements. In fact, EPA set these mandatory testing requirements based upon whether the toxic pollutants appeared in concentrations above 10 ppb. (See discussion in preamble to the Consolidated Application Forms, 45 FR 33516, May 19, 1980.) EPA periodically revises the testing requirements in the NPDES regulations, based upon consideration of this or any new data. For example, EPA suspended testing in certain categories where further data indicated that toxic pollutants were not likely to be present in all facilities within the category (see discussion of suspensions below). In recognition that it may be more burdensome for applicants to predict what pollutants may be discharged, EPA has established a threshold to relieve applicants of some of the testing burdens. Because of the greater degree of certainty of the presence of pollutants in primary industry process discharges, relief in the form of a threshold is not justified.

Another commenter requested that EPA clarify the status of suspensions of the mandatory testing requirements for organic toxic pollutants. EPA suspended mandatory testing requirements for all organic toxics in the Coal Mining Point Source category on January 8, 1981 (46 FR 2054) and for some or all organic toxic pollutants in the Textile Mills, Ore Mining and Dressing and Porcelain Enameling Point Source Categories on April 20, 1981 (46 FR 22584). On July 1, 1981, EPA also suspended mandatory testing for some or all organic toxic pollutants in the Gum and Wood Chemicals; Leather Tanning and Finishing; Paint and Ink Formulation; Photographic Supplies; Petroleum Refining; Pulp, Paper and Paperboard; and Steam Electric Power Generating Point Source Categories (46 FR 35090). These requirements are still suspended. EPA intends to propose regulations in the future that will make the changes to the mandatory testing a permanent regulation change.

*4. EPA Action.* In response to public concerns over the 100 ppb threshold provision, today's rule modifies the proposal. The final rule requires applicants to submit quantitative data for any toxic pollutant they know or have reason to believe is present in the discharge above 10 ppb. For four pollutants (acrolein, acrylonitrile, 2,4-dinitrophenol, and 2-methyl-4,6

dinitrophenol), we are establishing a higher threshold of 100 ppb. Applicants must continue to identify any toxic pollutant they know or have reason to believe is present but below these threshold levels applicants have the option to either supply quantitative data or explain why the pollutant is known or believed to be discharged.

Several persons requested that we clarify whether the inclusion of the requirement to sample and test the parameter "total phenols" in Item V–C of NPDES Form 2c is intended to classify total phenols as a toxic pollutant. While all other pollutants covered by Item V–C are toxic pollutants, EPA recognizes that this parameter (total phenols) using the 4-aminoantipyrine (4AAP) standard method, measures both toxic and non-toxic pollutants. Total phenols are covered in Item V–C merely for the purpose of specifying the type of testing and reporting that is required. EPA is modifying the Title to Appendix D to Part 122 to clarify that total phenols are included in Item V–C only for testing purposes and not to classify the parameter as a toxic pollutant.

Therefore, an applicant would be eligible for a variance under sections 301(c) or 301(g) from a BAT permit limit on total phenols upon a demonstration (*e.g.*, by GC or GC/MS) that either those toxic phenolics listed under section 307(a) of the CWA are not present or that each section 307(a) toxic phenolic present is at a level below that required by BAT or is directly controlled by a BAT effluent limitation. Where limitations on total phenols (as measured by 4AAP) are being used to control section 307(a) toxic pollutants not otherwise limited in the permit, a variance cannot be granted unless the total phenols limitation as an indicator for control of the toxic pollutants is replaced by another indicator pollutant not the subject of the variance request or individual limits are placed on the toxic or conventional pollutants in question.

(c) Certain Conventional and Nonconventional Pollutants

*1. Existing rules.* Section 122.21(g)(7)(iii)(B) [CPR 122.53(d)(7)(iii)(B)] and Item V–B of Form 2c require applicants to submit quantitative data for certain conventional and nonconventional pollutants identified in the regulations (Part 122, Appendix D, Table IV) if they know or have reason to believe the pollutant is present in the discharge. Like the other testing requirements, this provision is intended to supply adequate information on the contents of the discharge to establish permit conditions.

*2. Proposed change.* As with the testing requirements for toxic pollutants, industry litigants were concerned that this requirement was overly broad in that it required testing for every pollutant believed present, regardless of the amount. In response, the Agency again proposed to establish a screening criterion for testing purposes. Since a concentration-based threshold was inappropriate for a number of the pollutants in this group, EPA proposed that applicants be required to submit quantitative data only if the pollutants were either directly or indirectly (through an indicator) limited in an applicable, promulgated effluent limitation guideline. Under the proposal, permitting authorities would rely upon guidelines to indicate when pollutants were of concern and would supplement data through subsequent requests to the applicant. If quantitative data were not required because the pollutant was not limited in a guideline, applicants would still be required to identify any pollutants that they know or have reason to believe are present and explain why the pollutants are expected in the discharge.

*3. Comments and responses.* Most commenters expressed general support. However, one stated that all dischargers should be required to submit data on pollutants that they have used, handled, or generated within the previous five years, or which they know or have reason to believe are present in the discharge. Because the potential for extensive, potentially unneeded testing is great and the pollutants subject to this application requirement are not among the 126 toxic pollutants of primary concern, we consider this suggestion overly broad. While information on such pollutants may be useful, after general consideration of testing burdens and the value of the information in setting permit conditions, we have concluded that for these pollutants it is not always necessary to require extensive up front submission of testing results through the application form unless they are limited by a guideline. The Director may still obtain quantitative data if he determines that additional information is necessary. Otherwise, data on pollutants regulated by a guideline and a narrative description of the reason other pollutants in this category are expected to be discharged should provide sufficient information to develop adequate permit limitations.

Another commenter observed that in the case of discharge categories for which no effluent limitations guideline has been promulgated, no testing is required by the proposal. It is true that the proposal would not require testing for such discharges as part of the application. However, the applicants must still identify these pollutants expected to be present in the discharge and explain why they are present. If additional information is needed to decide whether to establish effluent limitations, the Director can use his authority under § 122.21(g)(13) [CPR § 122.53(d)(13)] to obtain the additional information. EPA expects that in these cases, the Director will closely examine the circumstances surrounding the discharge, including the applicant's explanation of why the pollutant is expected to be present, and request information whenever pollutants may be of concern.

*4. EPA action.* EPA is adopting the modification to § 122.21(g)(7)(iii)(A) as proposed. The change will reduce testing requirements for many dischargers, while not affecting EPA's ability to obtain necessary information concerning the pollutants. Since applicants must still submit quantitative data whenever the applicable effluent limitation guideline regulates the pollutant, EPA can write adequate permit conditions for many of the more significant discharges without additional requests for information. For discharges not covered by effluent limitation guidelines, the permitting authority may rely upon its authority to request additional information to ensure that adequate data are available to establish permit limitations. The final rule is a reasonable compromise between the need to avoid extensive, unnecessary testing and the need to assure that enough information is readily available to allow the Director to develop an appropriate permit.

*(3) Sampling (40 CFR 122.21(g)(7) [CPR § 122.53(d)(7)])*

1. *Existing rules.* Section 122.21(g)(7) specifies the type of sampling that applicants are required to perform to obtain quantitative data required by the application. Under the regulation, applicants must use 24-hour composite samples for all testing, except that grab samples must be taken for seven named pollutants (pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, and fecal coliform).

2. *Proposed changes.* EPA's sampling requirements were considered too restrictive by a number of litigants. EPA proposed to revise the sampling requirements to allow the expanded use of grab samples in three cases. Grab samples in lieu of composite samples

would be allowed for holding ponds and other impoundments with a retention time of over 24 hours. Applicants could also use grab samples for storm water discharges, but would be required to take one grab sample for each hour of discharge up to a minimum of four grab samples for discharges of four or more hours duration. The proposal would also allow the Director to waive composite sampling if the applicant demonstrates that use of an automatic sampler is infeasible and that the minimum of four grab samples would be representative of the discharge. The proposed changes were intended to allow greater sampling flexibility where use of grab samples would still provide representative data and to recognize the impracticalities of obtaining composite samples of storm water discharge.

3. *Comments and responses.* All comments received supported the proposal. Several persons stated that there was no need to specify a particular sampling method where other methods can produce reliable data. EPA is convinced it *is* appropriate to specify these methods because sampling methods affect the reliability and accuracy of analytical data submitted on the application. For most discharges, EPA requires composite samples since these samples usually produce the most reliable and representative data for assessing the environmental impact of the discharge over time. The existing regulations require grab samples for seven pollutants because storage of the sample for the time to take a 24-hour composite sample makes evaluation of the parameter difficult or impossible (e.g., temperature). EPA recognizes that in certain cases where applicants can generate reliable data through other methods, it is appropriate to increase flexibility. Therefore, EPA will now allow grab samples for storm water discharges because the unpredictable and infrequent nature of such discharges makes composite sampling very difficult. EPA is also allowing grab samples for holding ponds or other impoundments with 24-hour retention time and, at the Director's discretion, other discharges if use of an automatic sampler is infeasible. The one grab sample minimum for holding ponds or other impoundments applies both to holding ponds at the end of the treatment system and to those that are themselves treatment systems. This change should reduce sampling costs for applicants while not appreciably reducing the reliability of the application data.

One commenter supported EPA's proposed change as it affects storm water discharges. Composite sampling may not be possible for some storm water discharges and hourly sampling (for the first 4 hours) up to a minimum of four grab samples should be sufficient to accurately reflect the discharge. The regulations do not specify any particular time during each hour that applicants must test although applicants must take samples that are representative of the discharge. Since, in many instances, the first discharge of pollutants after a rainfall is the most significant, applicants should wherever feasible, take their first grab sample during the first quarter hour of storm water discharge.

4. *EPA action.* For the reason stated above, today's final rule is adopted as proposed.

*(4) Potential Discharges* (40 CFR 122.21(g)(10) [CPR § 122.53(d)(10)])

1. *Existing rules.* The NPDES regulations require permit applicants to list any toxic pollutant that is expected to be discharged during the following five years at more than twice the level reported in the application. The requirement is intended to provide notice of anticipated discharges to allow permit writers to establish limitations at the time of permit issuance and ensure installation of adequate control technology prior to changes in the discharge.

2. *Proposed changes.* Litigants argued that acurate prediction of future discharges was exteremely difficult. They also stated that changes in discharge levels were inherent given the analytical variability in pollutant testing. They feared the requirement could mean that failure to properly predict or report on such changes would expose them to liability for filing an incorrect application. EPA proposed to delete § 122.21(g)(10) since the information on potential discharges, although useful, was not essential to writing adequate permits. Additionally, EPA relied upon § 122.42(a) [CPR § 122.61(a)], under which permittees would be required to notify the Director during the term of the permit of toxic pollutant discharges exceeding five times the application value, thus allowing permit modification if necessary.

3. *Comments and responses.* One commenter objected to the deletion of this application requirement, stating that the information allows establishment of permit limits and installation of control equipment prior to discharge. Several other commenters supported the proposal stating that accurate prediction was impossible given analytical variability.

EPA agrees that the establishment of permit limitations and installation of any appropriate treatment equipment prior to the discharge or increased discharge of toxic pollutants is an important goal. However, exact prediction of future discharges is not always possible, and only in some cases will information on future discharges be sufficiant to allow the permit writer to establish such limitations at the time the permit is issued. Therefore, the burden on applicants of predicting future discharges does not appear justified in light of the generally speculative nature of making future discharge level predictions. Under § 122.42(a), permittees must notify the Director whenever the routine or frequent discharge of a toxic pollutant exceeds the higher of 100 ppb or five times the value reported in the application. This should generally be sufficient to allow the Director to modify the permit to impose permit limitations or other conditions if appropriate. In addition, most significant increases will also be associated with process changes that dischargers must still report under §§ 122.42(a) or 122.41(l)(1) [CPR § 122.7(l)(1)]. Of course, applicants are encouraged to provide the permit writer with any relevant information on planned new or increased discharges expected during the term of the permit being sought (usually five years).

4. *EPA action.* For the reasons stated above the final rule adopts the provision as proposed and deletes § 122.21(g)(10). (A new paragraph § 122.21(g)(10) is added by revisions to the storm water regulation. See B., below.)

*(5) Used or Manufactured pollutants (40 CFR 122.21(g)(9) [CPR § 122.53(d)(9)], 122.42(a)(2) [CPR § 122.61(a)(2)], 122.44(e)(1)(ii) [CPR § 122.62(e)(1)(ii)], 122.62(a)(13) [CPR § 122.15(a)(ix)])*

1. *Existing rules.* Four provisions of the NPDES regulations relate to application, notification, and control requirements for pollutants that the discharger uses or manufactures as intermediate or final products or byproducts. These requirements affect all aspects of the Toxic Control Strategy.

Applicants must identify all toxic pollutants that the applicant does or expects to use or manufacture within the next five years (§ 122.21(g)(9) [CPR § 122.53(d)(9)] and Item VI of Form 2c). Examination of such pollutants can assist in the establishment of permit limitations by supplementing quantitative data that the discharger has submitted. The NPDES regulations also require the Director to establish permit limitations on all toxic pollutants that

the discharger does or may use or manufacture § 122.44(e)(1)(ii)) [CPR § 122.62(e)(1)(ii)]. Permitees must notify the Director whenever they begin or expect to begin to use or manufacture a toxic pollutant that was not reported in the permit application (§ 122.42(a)(2) [CPR § 122.61(a)(2)]. Based on such information, the Director has authority to modify the permit to then include limits for these toxic pollutants (§ 122.62(a)(13)) [CPR § 122.15(a)(5)(ix)]).

2. *Proposed changes.* A number of litigants objected to EPA's regulations dealing with used or manufactured toxic pollutants, suggesting that EPA had authority only to regulate the discharge of pollutants. Since not all pollutants that are used or manufactured by a permittee are necessarily discharged, EPA determined that the requirements might be unnecessarily broad. Although EPA did not agree that it lacked authority to regulate such pollutants, EPA proposed to delete all four provisions relating to the use or manufacture of toxic pollutants and thereby avoid unnecessary application requirements, and the imposition of permit limitations on pollutants that are not discharged. EPA concluded that requirements in the permit application for obtaining data on the actual discharge of pollutants and authority to impose permit limitations on any of these pollutants would provide adequate control of toxic pollutants.

3. *Comments and responses.—a. Comments on application and notification requirements.* Several commenters opposed the deletion of the application and notice requirements. One State indicated that EPA should retain the existing regulations to allow imposition of permit limitations and installation of control technology prior to discharge. Several others commented that, at a minimum, information on toxic pollutants currently used or manufactured was necessary. Another State added that the information from the application was very useful during inspections of a permittee. Other commenters supported the elimination of the application requirement to predict future use or manufacture due to the difficulty of making such predictions. These commenters also supported the proposal as it related to permit conditions and notification requirements stating that it is more appropriate to concentrate on pollutant discharges than on their use or manufacture.

EPA has carefully considered the comments and concluded that the proposal to delete all four provisions went too far in eliminating regulation of used or manufactured toxic pollutants. Since pollutants that are used or manufactured at a facility frequently have some potential to be discharged, even if unintentionally, it may be appropriate to regulate them. Information on the use or manufacture of pollutants allows permit writers to establish appropriate conditions to control the discharge of pollutants. These controls may take the form of permit effluent limitations on the pollutant. In some cases, permit writers may determine that the imposition of Best Management Practices (BMP) conditions in permits will be a more effective means to control the pollutant by reducing the possibility of actual discharge. (For example, BMPs may be appropriate where a potential for discharge exists due to leaks or spills from storage facilities.) Quantitative data requirements will generally not provide information on all used or manufactured toxic pollutants since the applicant may not have reason to believe the pollutants will be discharged. Thus, permit writers would not have adequate data to impose limitations on these pollutants. Additionally, as the commenter noted, this information can assist authorities in performing compliance inspections.

However, instead of requiring speculative prediction of future use or manufacture and notification when the discharger begins to use or manufacture a toxic pollutant, the regulations will only require applicants to submit information on toxic pollutants currently (at the time of application) used or manufactured. This will be sufficient for permit writers to impose adequate permit limitations since the permit must be renewed at least once very five years. The notification of pollutant use or manufacture during the entire permit term is more burdensome than the one time application requirement and has been eliminated to reduce permittee burdens.

EPA recognizes that for some dischargers the obligation to report all used or manufactured toxic pollutants may be difficult or even impossible to meet, particularly when there are numerous toxic components in a substance. For example, applicants that use chemical solvents purchased under a brand name may be unaware of or unable to ascertain the specific toxic pollutant components that are in the solvent. To reduce these burdens, the regulation will allow the Director to modify or waive the requirement to list all used or manufactured toxics pollutants if the applicant can demonstrate that it would be overly burdensome. For example, the Director could modify the application provision for a discharger to require only a listing of solvents by brand name and then use the information, along with other information available to him (such as toxicity testing results or water quality data), in conjunction with his best professional judgment, to decide whether more exact information is needed. Even where the waiver is granted, the Director can use his authority under (§ 122.21(g)(13) [CPR 122.53(d)(13)]) to request additional information where necessary. This change will reduce burdens for many applicants, without reducing the Director's ability to obtain needed information.

While data on future use and manufacture might also be useful to allow the imposition of permit limitations prior to any potential for discharge, this value is outweighed by the burdens it creates for applicants. Some applicants will be unable to predict future use or manufacture of toxic pollutants, making the information of little value because of its speculative nature. The permitting authority should still receive notice when the permittee has reason to believe these pollutants will be discharged at or above 100 ppb (see § 122.42(a)(1)), and the Director may then impose such permit conditions as are necessary.

One commenter supporting the proposed change to the application stated that the existing requirement to report used or manufactured toxic pollutants in the permit application could lead to the divulgence of confidential business information. Data on currently used or manufactured pollutants are needed to ensure that the permit contains adequate conditions to control potential or actual discharges. Since the CWA specifically provides that application forms must be available to the public (section 402(j)), EPA has no discretion to keep portions of the application confidential (see § 122.5(c) [CPR § 122.19(c)]). EPA recognizes the possibility that some confidential information may be included in the listing of used or manufactured pollutants. However, EPA believes that the need for this information to assure adequate environmental protection in general outweighs the burden to applicants. EPA, therefore, will continue to require submission of data on current use or manufacture. The Agency expects, however, that some of the commenter's concerns may be alleviated by the deletion of the requirement that permittees predict future use or manufacture. In addition, the Director can exercise his discretion in truly

burdensome situations to modify or waive the requirement to list all pollutants currently used or manufactured where this information is not necessary to establishing permit limitations.

*b. Comments on permit limitations.* Several commenters supported the proposed deletion of the requirement that permits contain limitations on all toxic pollutants the permittee does or may use or manufacture. Because it requires effluent limitations even when the Director determines that they are unnecessary or where other means to control pollutant discharge, such as BMPs, are more appropriate, the Agency agrees that this regulation is unnecessary and overly restrictive and that it is better to allow the Director discretion in determining what limitations are appropriate. The Director still must impose limitations on any pollutant regulated by an applicable guideline and has authority under § 122.44 to impose permit limitations on any pollutant that may be of concern.

Another commenter supported the proposed deletion of the requirement to impose permit limitations, but suggested that we modify § 122.44(e)(1)(i) [CPR § 122.62(e)(1)(i)] which requires the Director to impose permit limitations on any pollutant that may be discharged at levels above BAT. The suggested modification was to require the establishment of such limitations for pollutants discharged at levels below BAT, but above water quality standards. Since permitting authorities have adequate authority to impose any limitations that are necessary to ensure compliance with State water quality standards [§ 122.44(d), [CPR 122.62(d)]] it is unnecessary to modify the regulation as suggested.

4. *EPA action.* For most of the provisions, the final regulation is identical to the proposal. Sections 122.42(a)(2), 122.44(e) (i) and (ii), and 122.62(a)(13) are deleted by today's rule. However, in response to commenters' concerns, EPA will retain the requirement that applicants list all toxic pollutants that are currently used or manufactured as an intermediate or final product or byproduct (§ 122.21(g)(9)—Item IV of Form 2c). Applicants will no longer be required to predict future use or manufacture. The regulation will also allow the Director to modify or waive the currently used or manufactured application requirements if the applicant can demonstrate that it would be overly burdensome.

*(6) Toxics Notification* (40 CR 122.42(a) [CPR § 122.61(a)])

1. *Existing rules.* The third element of the Toxic Control Strategy is the provisions for obtaining follow-up information concerning discharges during the permit term. One mechanism for providing such information is § 122.42(a) [CPR § 122.61(a)] which requires all industrial permittees to notify the Director when an activity has occurred or will occur that will result in the discharge or a toxic pollutant that is not limited in the permit. The permittee must provide such notice if the discharge exceeds the higher of 100 ppb (or 250 ppb for four pollutants identified in the regulation) or five times the concentration level reported for the pollutant in the application. This report is intended to ensure notification of new or increased toxic pollutant discharges during the permit term and allow for any appropriate permit modification.

2. *Proposed changes.* Industry litigants alleged that the regulation required continual notification because of the analytical variability when testing for the presence of pollutants at 100 ppb. This provision was not intended to require notification of daily fluctuations in pollutant readings, but rather to require notice of actual changes in the amount of the pollutants being discharged. EPA therefore proposed to modify the regulation to more accurately reflect the intent. Permittees would be required to notify the Director of the discharge of toxic pollutants exceeding threshold levels (the higher of 100 ppb or five times the concentration reported in the application) but only for toxic pollutants discharged on a routine or frequent basis, since these discharges are most appropriately controlled through permit limitations.

The proposal also required permittees to report nonroutine or infrequent discharges of a toxic pollutant not limited in the permit, if a single occurrence exceeds 10 times the value reported in the application, or 500 ppb, whichever is greater. EPA stated that infrequent and nonroutine discharges are still of concern, but are not as likely to be controlled through permit limitations.

3. *Comments and responses.* Several commenters supported the proposal because it would eliminate unnecessary burdens and concentrate on discharges that have a regulatory significance. EPA agrees that the proposal will eliminate burdens for dischargers, although the Agency would not characterize non-routine and infrequent discharges as lacking regulatory significance. The notification requirement is intended to provide information on new or increased toxic pollutant discharges thereby allowing the imposition of permit limitations (see 45 FR 33521, May 19, 1980). Non-routine and infrequent discharges may still be significant, not due to a continuing discharge problem, but rather because many of these discharges are pollutant spills or other irregular events. However, since permitting authorities are less likely to modify the permit to impose limitations to control such discharges, EPA has established a higher threshold for reporting those toxic discharges. This higher threshold will reduce reporting burdens for permittees, while still alerting the Director to possible problems with the discharging facility that would require permit modification. In addition, permittees may have an independent obligation to report the spill situations not addressed by the NPDES permit under section 311 of the CWA.

Several commenters supported the proposal preamble statement that the notification requirement was not intended to require continuous monitoring. The Agency reiterates that the notification requirements of this provision are not intended to impose on a permittee a burden of continuous monitoring throughout the term of the permit. Rather, if the permittee discovers through any means available (*e.g.*, routine monitoring required by the permit, independent monitoring done by the permittee, or a professional judgment that a reasonable potential for discharge exists based on a knowledge of changes in the facility or process operations) that it now expects toxic pollutants not limited in the permit to be discharged, the permittee must notify the Director. In determining whether a discharge is routine or frequent within the level specified, the permittee should examine the circumstances of the discharge and the operations of its facility or activity to determine whether additional self-monitoring is necessary to make an accurate determination of whether it is routine or frequent.

One commenter stated that threshold levels were inappropriate for notifications of the new discharge of toxic pollutants. While EPA recognizes that requiring dischargers to report any discharge of new toxic pollutants would provide the maximum possible information, this could impose an extremely large burden on permittees to report toxic pollutants at extremely low levels. Unlike the permit application which requires the submission of information only once every five years, permittees must report throughout the

permit term under the notification requirement whenever a toxic pollutant is discharged. Therefore, the Agency has established a notification level to relieve dischargers from having to report all new discharges. The threshold level is set to require reporting a toxic discharge not limited in the permit in excess of 100 ppb or when the discharge of a pollutant exceeds five times the value reported on the application.

One commenter suggested that EPA impose permit limitations based upon the discharge values reported in the application. The Agency proposed such an application-based permit limit approach twice, and rejected it on the basis of extensive public comment. (See 45 FR 33516, May 19, 1980; 44 FR 34346, June 14, 1979; 43 FR 37078, August 21, 1978). EPA's decision was based on the inadequacy of data on wastestream variability and the problem of batch processes. EPA also concluded that the application-based approach could have imposed severe monitoring costs on applicants and permittees and that a more focused approach was preferred. The Agency continues to support the reasoning for the decision.

Several commenters claimed that the higher notification level could result in significant pollutant discharges without notification. In addition, these commenters suggested that the lack of a definition of routine or frequent discharge could also allow discharges without notification. EPA recognizes that some discharges below 500 ppb may be significant. However, the primary purpose of § 122.42(a) is to provide information on new or increased dischargers that may warrant permit modification. Since discharges subject to the higher threshold are infrequent and non-routine, the Director is generally less likely to modify the permit to impose limitations. Therefore, EPA has established a threshold at which the significance of the discharge increases the likelihood of permit modification.

EPA would also like to clarify the meaning of routine or frequent discharges. The lower threshold levels apply to any discharge that is either routine or frequent, not necessarily both. Routine discharges are those that occur on some regular basis (whether once a week or four times a year). This does not mean that routine discharges are only those that occur with clockwork regularity. Any discharge that the permittee expects will occur as a result of normal plant operation is likely to be routine. Thus, a facility that has a large holding pond from which it discharges several times a year would be subject to the routine discharge standard.

Discharges that occur mor than twice a year are frequent, whether or not they are routine. One-time spills are an example of infrequent discharges. These infrequent discharges are less likely to be controllable through permit limitations.

4. *EPA action.* After review of the comments, EPA has decided to promulgate the rule as proposed. Section 122.42(a) requires an existing industrial permittee to notify the Director when some activity has occurred or will occur causing it to discharge toxic pollutants which were not previously limited in the permit. In general, when such a discharge of a toxic pollutant occurs on a routine or frequent basis, the permittee must notify the Director if that discharge exceeds 5 times the level reported in the permit application form, or 100 ppb, whichever is higher. The permittee must also notify the Director when any one occurrence of a discharge exceeds 10 times the reported value or 500 ppb, whichever is greater.

*(7) Toxicity Limits* (§ 125.3(c)(4))

1. *Existing rules.* Most NPDES permit effluent limits are expressed as numeric limitations for specific pollutants. In addition to limiting specific chemicals, several generic pollutant parameters which simultaneously measure the effect of a number of distinct chemical substances are commonly limited (e.g., biochemical oxygen demand (BOD), chemical oxygen demand (COD), color, etc.). The NPDES regulations also authorize effluent limitations expressed in terms of effluent toxicity. Under the regulations, toxicity limits must reflect appropriate requirements of the Act (e.g., technology-based requirements or water quality standards). Toxicity limitations are useful where chemical limitations are either inadequate or infeasible (see 45 FR 33523, May 19, 1980). Permitting authorities determine compliance with toxicity limitations through biomonitoring of the effluent.

2. *Proposed changes.* Industry litigants had questioned the appropriateness of setting effluent toxicity permit limitations, particularly in the absence of an Agency policy. There was also some concern over the accuracy with which these limitations could be established and compliance measured. At the time of proposal, EPA was studying toxicity testing and its role in the NPDES program. EPA, therefore, proposed to delete § 125.3(c)(4) until we could complete our review and develop a policy for using toxicity-based permit limitations. Recognizing the usefulness of toxicity data as an assessment device in evaluating wastewater discharges, EPA continued to encourage its use for this purpose. Nevertheless, until EPA could develop a policy towards using biomonitoring and toxicity-based permit limitations, the use of actual toxicity-based limitations was discouraged.

3. *Comments and responses.* Several commenters stated that there is adequate information to justify the use of toxicity limitations in conjunction with other limits. These commenters argued that in many cases toxicity testing is a more valid approach than attempting to address all of the chemical pollutants and provides the only means to assess the actual impact to receiving water biota. One commenter also observed that toxicity-based limits created flexibility to use all available information to set limits. Other commenters expressed concern that the state of the art was not adequately developed for effective use of toxicity-based limitations.

Since the proposal, EPA has extensively considered the use of toxicity as a parameter for evaluating the effects of discharges and establishing permit limitations. EPA has concluded that toxicity testing is sufficiently refined to be used in setting effluent limitations, and has developed a policy for using toxicity testing in conjunction with chemical limitations to achieve water quality standards. This policy was issued on February 3, 1984 and published in the **Federal Register** (49 FR 9016, March 9, 1984). The policy explains that, in addition to enforcing specific numerical criteria, EPA and the States will use biological techniques and available data on chemical effects to assess toxicity impacts. In many cases, imposing effluent toxicity limits will be a better (and more feasible) means to prevent adverse water quality impacts and control toxic pollutants than attempting to address all of the individual chemicals in the effluent. Toxicity limitations can be particularly effective in controlling the cumulative impact of toxic pollutants in complex effluents. Additionally, as one commenter observed, site-specific characteristics of the receiving waters can also affect pollutants' toxicity. Analytical methods and information are available to determine controls to reduce toxicity through toxicity reduction evaluations. Therefore, EPA has decided to make no change in the regulation.

States commenting on the proposal were opposed to the change, arguing that they had effectively used toxicity limits for years. These States feared that EPA's revision would undermine their ability to use this permit and enforcement mechanism. EPA

recognizes that many States have successfully used permit limitations based on overall effluent toxicity and that the proposed deletion of the regulation authorizing toxicity limits and our preamble statements discouraging their use could undercut these State efforts. EPA's intention was only to announce EPA's plan to limit use of toxicity limitations prior to development of a formal policy, not to affect State use of toxicity limitations. EPA has now issued a policy to strongly encourage States to use both chemical and biological techniques, including consideration and elimination of total toxicity, to assess and control toxic pollutants.

Several commenters argued that EPA has no authority to prescribe toxicity permit limitations. The Agency has consistently taken the opposite position. EPA has authority to impose toxicity permit limitations either on a case-by-case basis under section 402(a)(1) or as necessary to implement State water quality standards. The definition of effluent limitations in section 502(11) does not indicate that the limitations must be either numerical or identify a particular pollutant. Additionally, toxicity limitations are similar to other generic pollutant parameters controlled in effluent limitations guidelines and used in permits, such as BOD, some of which are expressly authorized by the CWA (see section 304(a)). Similarly, toxicity limitations are also authorized when necessary under section 301(b)(1)(c) to meet State water quality standards. Section 308 of the CWA clearly authorizes EPA to require the generation of any information reasonably necessary to carry out its responsibilities; it specifically authorizes requirements for biological testing and other information as needed to establish permit limits.

Two commenters objected to the use of toxicity permit limitations in the absence of approved section 304(h) test methods. The absence of approved section 304(h) test methods is not sufficient reason to refrain from using available methodologies, since it does not mean that there are not well-established analytical procedures. Permitting authorities should use their judgment in determining which methods to use. In requiring toxicity monitoring or specifying a permit toxicity limitation, the regulatory authority must specify in the permit the analytical methodology to be used until methods are established under 304(h). EPA has successfully used this approach for a number of years for the priority pollutants for which there are not yet approved test methods.

One commenter stated that toxicity limits could subject discharges to changing treatment requirements which may include technologies different from those contemplated by an applicable effluent limitations guideline. The CWA requires compliance with two principal requirements: technology-based standards and water quality standards. EPA and the States will use biological techniques and available data on chemical effects to evaluate and control toxicity impacts primarily to achieve water quality standards. Therefore, the use of toxicity to define water quality requirements does not impose any burdens not already required by the CWA. To the extent toxicity limitations are technology-based, the permitting authority must consider the statutory factors in the development of the limitations, as required for any other technology-based limitation.

*4. EPA action.* As noted, the primary reason for proposing to delete the regulation was the absence of a formal EPA policy for the use of toxicity limits. EPA issued a policy which develops an integrated strategy for use of biological and chemical discharge control methods. Issuance of the policy will also replace our statement in the proposed rule discouraging use of toxicity limits. To enable EPA to implement the policy now issued, today's final rule retains the existing regulation authorizing the use of toxicity effluent limitations.

**B. Storm Water Runoff Discharges (40 CFR 122.21 [CPR § 122.53], 122.22 [CPR § 122.6], 122.26 [CPR § 122.57])**

*1. Background.* The appropriate means of regulating the discharge of storm water into the waters of the U.S. has long been a matter of concern to EPA. In its first attempt to resolve the issue, EPA, in 1973, distinguished among various types of storm water. At that time, the Agency promulgated regulations which exempted certain sources, among them storm water runoff discharges uncontaminated by industrial or commercial activity, from the requirement to obtain an NPDES permit. EPA maintained that, although these discharges fell within the definition of point source, they were ill-suited for inclusion in the NPDES permit program and better dealt with through non-point source controls. It was reasoned that pollutants are best eliminated from storm sewers by "process changes" which prevent pollutants from entering rainwater runoff rather than by treating the discharge by the traditional "end-of-pipe" NPDES permit method. In addition, EPA determined that to issue permits to the tremendous number of storm water sources would be adminstratively unworkable within the framework of the NPDES permit program.

Shortly thereafter, the Natural Resources Defense Council (NRDC) challenged EPA's authority to exempt categories of point sources from permit requirements under the CWA (*NRDC, Inc.* v. *Train*, 396 F. Supp. 1393 (D.D.C. 1975)). The U.S. District Court for the District of Columbia held that EPA could not lawfully exempt discharges which it identifies as point sources from regulation under the NPDES permit program. Although denying EPA the authority to exempt point sources from permit requirements, the Court did recognize the Agency's substantial discretion to define what activities constitute point and non-point sources. Furthermore, in response to EPA's administrative burden argument, the Court recognized EPA's discretion to use administrative devices, such as area permits, to manage its workload. (Id. at 1401–2).

On appeal, the U.S. Court of Appeals for the D.C. Circuit affirmed the lower court decision. (*NRDC* v. *Costle*, 568 F.2d 1369 (D.C. Cir. 1977)). On March 18, 1976, in response to the Court decision in *NRDC* v. *Train*, EPA published final storm water regulations which required NPDES permits for all storm water discharges, other than rural runoff, which the Agency contended was better considered non-point sources. Changes to these regulations were reflected in the separate storm sewer regulations published on June 7, 1979, 44 FR (40 CFR 122.79); re-published on May 19, 1980 at 40 CFR 122.57, 45 FR 332290.

*2. Existing rules.* Section 122.26 [CPR § 122.57] describes those storm water runoff discharges which are considered "point source" discharges under the CWA and thus are subject to NPDES permitting requirements. Two types of storm water discharges are identified. First, a "separate storm sewer" is defined as a conveyance or system of conveyances primarily used for collecting and conveying storm water runoff which is located in an urbanized area as designated by the Bureau of the Census or which is designated by the Director on a case-by-case basis as a "separate storm sewer" for any of the reasons discussed in § 122.26(c). A second type of storm water discharge is a conveyance which discharges storm water runoff contaminated by contact with wastes, raw materials, or pollutant-contaminated soil from areas used for industrial or commercial activities. Such conveyances are not considered "separate storm sewers," but are nonetheless considered point sources

which must obtain NPDES permits. A conveyance or system of conveyances operated primarily for the purpose of collecting and conveying storm water runoff which does not fit within either of the above described categories is not considered a point source and need not obtain an NPDES permit.

Dischargers of storm water that are defined as point sources are required to apply for a permit and to submit the same information required of all existing industrial and commercial sources, such as discharge location and flow quantities. Analytical requirements are also set forth in the application. Applicants must submit information about the presence of pollutants in the discharge and, in some cases, quantitative data are required. (See discussion of application and testing requirements in Toxics Control Strategy section of the preamble.)

*3. Proposed changes.* Despite EPA's efforts to formulate an environmentally sound and administratively workable approach for the permitting of point source storm water runoff discharges, a number of litigants challenged the storm water provisions of the May 19, 1980 regulations. Industry representatives argued that EPA had not gone far enough in excluding storm water dischargers from the NPDES program. They asserted that most storm water discharges pose no significant environmental danger and therefore should not be considered point sources subject to permitting requirements. The Agency's use of the term "contaminated" to decide which storm water discharges are not "separate storm sewers" was also challenged as being overbroad and ambiguous. Finally, industry claimed that the permit application testing requirements for those storm water discharges classified as point sources were inappropriate and unduly burdensome.

Citing EPA's limited resources and the magnitude of its permit issuance tasks, industry questioned the value of EPA's accumulation of storm water runoff data via the application form. It is widely recognized that permitting of storm water runoff discharges not associated with industrial/commercial facilities is a low priority in EPA permit issuance and enforcement actions. The extremely large number of storm water runoff discharges potentially encompassed by the existing regulations represents an enormous permit writing burden. Even with the use of resource saving devices such as general permits, just developing the basis for permit terms and conditions for such a disparate group of sources is an enormous task. Industry claimed that EPA and the States would never get to this task in most cases, thereby making pointless industry's costly gathering and submission of application data. In light of the vast disparity among different types of storm water runoff discharges with respect to size, flow amounts, the seriousness of the pollutant loadings, and the economic feasibility of control measures, industry urged the Agency to adopt a new approach to the control of storm water.

Based upon the settlement agreement resulting from almost two years of negotiations, EPA proposed a new approach to the permitting of storm water discharges. (See 47 FR 52073.) In the November 18, 1982 proposal, EPA attempted to balance the environmental concerns associated with storm water discharges, the practical limitations of the NPDES permit as a tool for regulating storm runoff, and the realities of limited government resources. Elsewhere in the November 18 **Federal Register** notice, EPA proposed the suspension of certain existing application and testing requirements for storm water discharges pending completion of final rulemaking. The Agency took this step in recognition that its final action might make this potentially large and costly data base unnecessary.

*a. Definitions.* A central element of the proposal was the definition of those storm water runoff discharges which were point sources and thereby required to obtain NPDES permits. EPA attempted to distinguish between storm-related discharges that were best suited to control by permits as point sources and those that were not. In making this determination, EPA relied upon its authority under the CWA to define what are point sources and what are nonpoint sources (*NRDC, Inc.* v. *Costle,* 568 F.2d. 1369 (D.C. Cir. 1977), on appeal from *NRDC, Inc.* v. *Train,* 396 F.Supp. 1393 (D.D.C. 1975)).

In the proposal, the term "separate storm sewer" was eliminated and replaced with the term "storm water discharge." A storm water discharge was defined as a conveyance or system of conveyances primarily used for collecting and conveying storm water runoff that is either:

(1) Contaminated by contact with process wastes, raw materials, toxic pollutants, hazardous pollutants listed in Table V of Appendix D to Part 122, or oil and grease; or

(2) Designated as a storm water discharge by the Director.

A conveyance or system of conveyances operated primarily for the purposes of collecting and conveying storm water runoff that did not constitute a "storm water discharge" under this definition would not be considered a point source. This new definition was based on the determination that the excluded discharges were generally *de minimis* sources of pollution that Congress did not intend the Agency to regulate as point sources through the NPDES permit program.

Combined sewer discharges were not affected by the November 18 proposal.

*b. Application requirements.* The November 18 proposal also reduced the NPDES permit application requirements as they applied to point source storm water runoff discharges. Although under the proposal NPDES permits were required for "contaminated" storm water discharges, most such discharges were expected to pose far less environmental concern than typical industrial discharges for which the application requirements were designed. The belief was expressed in the proposal preamble that extensive testing and reporting would not be needed in order to issue adequate storm water permits.

The amount of information an individual applicant would be required to submit depended upon the particular category of storm water discharge involved. EPA divided those storm water discharges defined as point sources into two broad groups based upon their assumed potential for significant pollution problems. The first group were those which were likely to pose the relatively more significant pollution problems. Therefore, the proposed regulation subjected them to more extensive application and testing requirements. This first group consisted of three categories of storm water discharges:

(1) Those subject to specific effluent limitations guidelines or toxic pollutant effluent standards;

(2) Those designated as significant contributors of pollution by the Director under § 122.26(c); or

(3) Those located at industrial facilities in areas immediately adjacent to the industrial plant or in plant associated areas, if there was a potential for a significant discharge of runoff contaminated by contact with process wastes, raw materials, toxic pollutants or hazardous substances.

The third category covered conveyances which discharged rain runoff that had the potential for becoming contaminated by contact with raw materials, intermediate or finished products, wastes, or substances used in production or treatment operations. The

term "plant associated areas" included areas such as industrial plant yards, immediate access roads, drainage ponds, refuse piles, storage piles or areas, and material or product loading and unloading areas. The term excluded commercial areas located on plant lands separate from the plant's industrial activities, such as office buildings and accompanying parking lots, since contamination from process operations was not expected to occur there.

These Group I discharges would be required to submit NPDES applications that complied with all the requirements of § 122.21 [CPR § 122.53], and EPA permit application Forms 1 and 2c, with one exception. Group I applicants would generally not be required to submit *quantitative* sampling and analysis data. They were only required to indicate (in Items V–B and V–C of EPA application Form 2c) whether they believed any of the listed pollutants were present or absent and briefly describe why. Group I applicants would not be required under the proposal to test for pollutants they believed to be present. However, they were still required to test for seven listed conventional and nonconventional pollutants (§ 122.21(g)(7)(i)(A)—Item V–A of Form 2c). It was felt that this less expensive conventional pollutant testing would serve to alert the permit writers to possible significant pollution problems where they could request further testing for toxic and non-conventional pollutants. This approach was considered more economically and environmentally practicable than requiring Group I dischargers to test for the full range of conventional and non-conventional/toxic pollutants.

Group II consisted of all point source storm water discharges required to be permitted under § 122.26 that were not included in Group I. While these sources might be "contaminated", EPA asserted that since they were removed from pollutant generating commercial or industrial facilities, they would, logically, present less significant pollution problems than those in Group I. The reduced likelihood of the presence of significant amounts of pollutants justified even fewer application requirements. The proposed rules required only basic information necessary to identify the type, number and location of Group II storm discharges. The proposal eliminated all testing for and identification of pollutants for Group II.

In recognition of the intermittent and seasonal nature of storm water discharges, EPA further proposed that both Group I and Group II be allowed to estimate the average flow of their discharge. This estimate was to be based upon actual prior experience and the applicant would have to indicate the rainfall event upon which the estimate was based.

An additional simplification was proposed concerning the signatory requirements for Group II. Sections 122.22 (a) and (b) [CPR § 122.6 (a) and (b)] specify who is required to sign permit applications. EPA proposed to amend §122.22(b) to allow permit applications for Group II storm water dischargers to be signed by a duly authorized representative of the person or position identified in § 122.22(a) as responsible for signing applications. EPA decided this was appropriate since Group II storm discharges are much less complex than most point source discharges.

To allow sufficient time for both EPA and permittees to implement procedures reflecting the final promulgation of regulations covering storm water discharges, EPA proposed that existing unpermitted point source storm water dischargers be given six months from the date new final storm water regulations were issued to submit applications. For a discharger designated by the Director as a "storm water discharge" under § 122.26(c), the application would not be due until six months from the date of notification of its designation.

Finally, EPA proposed to revise § 122.26(a) to clarify that one permit could be issued covering all storm water discharges that are part of a storm water discharge system. In this case, each owner or operator of a discharge would be identified in an application form submitted by the owner or operator of the portion of the system discharging directly into the waters of the U.S. Any permit written to cover more than one owner or operator would have been required to identify the limitations applicable to each discharge and could not, without the source's consent, have imposed limitations on a source for discharges from another source.

On June 23, 1982, in conjunction with the settlement agreement on the storm water issues, EPA issued a non-enforcement letter. The letter indicated that while the proposal was pending, it was EPA's policy not to take enforcement action against storm water discharges other than those covered by an existing NPDES permit, subject to effluent limitations guidelines or toxic pollutant standards, or designated as a significant contributor of pollution. The "non-enforcement" policy also did not apply to existing enforcement actions. To be covered by the policy, storm water dischargers must submit new or amended applications, within six months after promulgation of new, final amended storm water regulations or within six months of designation as a storm water discharger under § 122.26(c).

*4. Comments and responses.* Its protracted gestation and thoughtful preparation notwithstanding, the storm water proposal generated more comment and controversy than almost any other section of the November 18 notice. Generally, trade associations and industries agreed with the proposed changes or stated they did not go far enough, while States and environmental groups opposed the proposal. Despite the numerous comments, there are only two major issues—which storm water discharges are point sources; and, what are the appropriate application and testing requirements for those that are.

*a. Definitions.* The most hotly contested portion of the proposed rulemaking is the same fundamental issue that has been disputed for over a decade. That is, what, if any, storm water discharges should be defined as point sources and thereby be subject to NPDES permit requirements. The Agency's proposal to classify as point sources those storm water discharges that are contaminated by contact with certain wastes, materials or pollutants received some support. However, it was also criticized on legal, technical, practical, and administrative grounds. Finally, a number of commenters stated that the proposal was flawed because it lacked sufficient clarity and specificity.

Those commenters supporting the proposal saw it as a common sense approach which appropriately focussed NPDES storm water permitting activities on discharges of concern. Several claimed that Congress did not intend the CWA to require regulation through NPDES permits of *de minimis* sources of pollutants and that the "contamination" screening criteria was a step in the right direction.

Comments criticizing the Agency's proposal as not going far enough emphasized several points. A number of commenters felt the proposal was still too all-encompassing and would classify as point sources some discharges, such as parking lots, which should not, and could not effectively, be controlled through the permit process. These comments were linked to concerns about EPA and States' ability to process thousands of applications from what were characterized as very minor discharges. Questions were also raised as to whether EPA had any practical

treatment processes in mind for these discharges. On the other hand, one commenter stated the proposal was too narrow in limiting "contamination" to a select list of pollutants and materials.

The use of the term "contamination" was criticized as being vague and ambiguous. Several commenters requested clarification in the form of a definition. They asked that specific threshold levels of pollutants; which would constitute contamination, and thereby trigger the permit requirement; be added to the regulation. Others questioned whether any acceptable, generic criteria could be established, and suggested that only case-by-case determinations on whether a discharge was a point source were appropriate.

These administrative and technical comments were bolstered on both sides by legal arguments. Those supporting a narrow use of the permit program for controlling storm water discharges contended that "pollutants" associated with storm water discharges were often naturally occurring and pandemic and that the CWA permit program was not intended to deal with this type of pollution problem but rather with pollutants relating to manufacturing and industrial processing. They asserted that Congress had specifically created non-point source provisions in the CWA to address the low pollutant levels and widespread occurrences often associated with runoff from rainstorms. In opposition to this approach, other commenters claimed the CWA requires storm water runoff to be regulated through the permit process regardless of the level of pollutants present in such discharges. This assertion notwithstanding, these same commenters questioned whether the Agency had a legally sufficient and technically supported basis for the distinction contained in the proposal.

The Agency recognizes that commenters have raised a number of legitimate issues with its proposal. However, although some uncertainty may exist about which specific discharges are properly classified as point sources, certain fundamental precepts are clear. Among these is that the best approach to deal with storm water related pollution problems, and the approach most consistent with the CWA, clearly falls between the extreme positions of not regulating any storm water discharges through the permit process, or of using NPDES permits to control all storm water which may potentially contain any pollutants. The Agency approach, set forth in the proposal, was a well-reasoned attempt at striking a balance. Under the CWA, Congress recognized that there are separate problems related to point and non-point sources of water pollution and different means to address them. Different sections of the Act deal with these distinct sources. Runoff from rain storms is best controlled as a point source in certain cases and as a non-point source in others. The Agency has the authority and the discretion to determine how this division should be made. In the preamble to the proposal, EPA cited the decision in *NRDC, Inc.* v. *Train*, 568 F.2d 1369 (D.C. Cir. 1977) in support of this authority. In their comments on the storm water proposal, NRDC alleged that EPA had improperly cited that case. NRDC is correct that in *NRDC, Inc.* v. *Train* the Court held that where the Agency defines a discharge as a "point source" it has no authority to exclude that source from the NPDES permit requirement. However, the Court in *NRDC, Inc.* v. *Train* additionally recognized that EPA has discretion to identify which sources are appropriately classified as point sources and which as non-point sources. This interpretation is upheld in subsequent cases, a number of which cite a statement by Senator Muskie in the 1971 debate on the FWPCA, "[G]uidance with respect to the identification of 'point sources' and 'non-point sources' . . . will be provided in regulations and guidance by the Administrator." (117 Cong. Record 38, 816 [1971]) Without the flexibility provided by this discretion, EPA would be hindered in its efforts to establish the most effective controls for various types of rain runoff.

Although EPA maintains that it has statutory authority to delineate between point and non-point sources, it does agree that to some extent both the existing regulation and the proposal were unclear. Further, EPA agrees that the proposal may have classified as non-point sources certain discharges which are best controlled under the NPDES permit program as point sources. The final regulation clarifies the point source/non-point source delineation as it applies to storm water runoff. Since EPA is persuaded by commenters that the proposal went too far in narrowing coverage of storm water under the NPDES permit program, the final rule maintains approximately the same coverage as the existing regulation.

The final rule classifies as a point source any storm water discharge which is located in an urbanized area, discharges from land or facilities used for industrial or commercial activities, or is designated by the Director as a point source. The data analyzed by the Agency to date do not support the proposed broad exclusion of storm water discharges from coverage as point sources. The final rule, therefore, retains comprehensive coverage of storm water discharges through the NPDES permit program. While EPA recognizes that in many cases these discharges may be better controlled as non-point sources, as several commenters pointed out, EPA may not exclude discharges without some basis. In fact, information currently available to the Agency, such as data recently available from EPA's Nationwide Urban Runoff Program (NURP) study, support the broad coverage of storm water discharges.

That study indicated there are both existing and potential pollutant problems with urban storm water runoff. NURP found significant instances of high levels of heavy metals (especially copper, lead and zinc) in urban runoff. Freshwater water quality standards (chronic) were exceeded for lead (94% of all samples), copper (82%), zinc (77%) and cadmium (48%). Nationwide, BOD loadings from runoff were estimated as comparable to that from secondary POTWs, while TSS loadings were estimated to be a factor of 10 higher than loadings from POTWs. Fecal coliform levels also indicated significant impacts from urban storm runoff, especially from runoff into lakes and shellfish harvesting areas. NURP considered a number of simple technologies which may significantly reduce levels of pollutants, although no economic analyses have been done.

Today's final regulation retains the classification of rural runoff as non-point sources. The Agency is convinced that most rural runoff cannot be effectively regulated by NPDES permits. In those cases where it can be, the regulations specifically classify the discharges as point sources (such as animal feedlots) or the Director has the authority to individually designate a discharge as a storm water point source. This is also consistent with Congressional intent that agricultural runoff be uniformly regulated through non-point source controls. This is indicated by the 1977 Clean Water Act amendments which exempted irrigation return flows from the point source definition. Congress' intent was to treat return flows similar to natural agricultural runoff, which was then already exempted by the Agency from point source control:

> * * * return flows from irrigated agriculture are indistinguishable from any other agricultural runoff, which may or may not involve a similar discrete point of entry into a watercourse. All such sources regardless of the manner in which the flow

was applied to the agricultural lands, and regardless of the discrete nature of entry point, are more appropriately treated under the requirements of section 208 * * *.

Senate Report, 4 Legis. Hist. Vol. 4, 668 (1977). See also Senate Debate of Conference report, 4 Legis. Hist. 527–8.) Consistent with this intent, EPA has excluded rural runoff that is not discharged from industrial or commercial lands or facilities.

EPA will continue to review existing information, including NURP data and any other available studies to determine appropriate control measures for storm water discharges. If these data indicate that further exclusions may be appropriate, EPA will propose such exclusions in the future.

Some improvement of clarity has been achieved by the repalcement of the old terms, "separate storm sewer" (existing regulation) and "storm water discharges" (proposal) with the more descriptive "storm water point sources". The existing regulation defined three different types of storm water discharges, two of which were point sources. The final regulation has only two categories—storm water point sources, which are subject to permit requirements as point sources, and other storm water discharges, which are not classified as point sources unless designated. EPA also agrees with the commenters who challenged as vague the use of the terms "contact," "contaminate," and "significant" in the proposed definitions of storm water point sources and Group I storm water discharges (proposed § 122.57(b) (1) and (2)). Some of these commenters wanted EPA to set numerical limits to define the point at which storm water became "contaminated;" however, the Agency lacks sufficient data to do this. To alleviate confusion, the final rule does not use these terms, but rather defines storm water point sources based solely on objective measures (i.e., by geographic criteria, rather than by the internal nature of the storm water).

On a related matter, other commenters requested that storm water discharges caused by diversion around an industrial facility, those contaminated by oil and grease, discharges from parking lots, and storm water discharges at natural gas compressor stations be classified as non-point sources. Although diversions from undistrubed areas around an industrial or commercial activity would not be considered industrial or commercial facility runoff for purposes of the storm water point source definition, nonetheless, they will be considered point sources if they are located in urbanized areas or designated a significant runoff source. With regard to discharges contaminated only by oil and grease, EPA has generally dropped the concept of contamination, so this point is now moot. No data or information were submitted to support the claims that parking lot runoff is not a pollution problem and therefore should be excluded from permit coverage. In fact, data from NURP indicate that discharges from parking lots may indeed present a problem and, therefore, EPA is maintaining coverage of such discharges as point sources. Similarly, no sufficient data were submitted to eliminate specific industrial categories from the point source definition. Therefore, EPA cannot exclude natural gas facilities that would otherwise fall within the definition of point sources.

Another commenter wished to exclude discharges that may be covered under the provisions of 40 CFR Part 112 (Spill Prevention Control and Countermeasure plans—SPCC). EPA disagrees. The provisions of Part 112 are meant to generally minimize the amount of pollutants that may need to be disposed of, by providing management practices to minimize spills. They do not replace the specific NPDES requirements necessary to control pollutant discharge levels when the resulting drainage is discharged into navigable waters.

Several commenters suggested the use of general permits to cover classes of storm water discharges, such as those discussed above. EPA agrees that this is an idea worthy of consideration and suggests that dischargers raise the concept with their permitting authority.

One commenter wanted more specification of the process by which storm water would be designated as a point source by the Director under § 122.26(c). This is a case-by-case decision which is highly site-specific and will be made by the Director on the basis of all information available, including application data. Of course, where the Director finds existing data are inadequate to make such a designation, he may request additional data from the owner or operator, including analytical testing, or may initiate data gathering on his own.

EPA recognizes that maintaining the broad coverage of the existing regulations will result in some burden for dischargers and the Agency. Lack of Agency resources and higher permitting priorities will mean that in many cases discharges which are classified as storm water point sources will not receive permits in the near future and will contribute to the backlog of minor permits. Nonetheless, this classification scheme will best allow the Agency to identify and target those storm water discharges which are amenable to NPDES permit control.

*b. Application requirements.* Comments on the proposed changes in the application and testing requirements for storm water point sources ranged from strong support to strong opposition. The two-tiered application approach was commended by many commenters as a practical recognition of the lesser likelihood of serious amounts of pollutants being present in Group II discharges. Generally, industry claimed it made little sense to require the same information for thousands of minor, intermittent storm water point sources as is required for process wastestreams. Thus, supporters stated the proposed changes would be substantial improvements by eliminating unnecessary analytical data and paperwork requirements, particularly the toxic testing requirements. Industry commenters asserted there was a limited likelihood that toxic pollutants would be present at levels of concern. These commenters pointed to the high costs and difficulty of obtaining samples that proved to have little value. Additionally, many commenters claimed that even though some rain discharges might be point sources, they were environmentally insignificant and, accordingly, less application data were needed. Supporters of the proposal also indicated that it was preferable to supplement data through requests to sources for additional information than to require thousands of sources to submit extensive data that would not be used.

Opponents of the proposal claimed the reduction in application testing requirements for rain runoff discharges deprived the permit writer of the information necessary to make a rational determination on appropriate permit terms and conditions. Several commenters questioned the logic of eliminating the requirement to monitor for toxics, especially since the proposed Group I classification on its face indicated there was a potential for discharge of toxic materials. EPA's claim that Group I testing data for conventional pollutants, such as BOD and TSS, would alert the permit writer to possible significant pollution problems was characterized as an "ignorance is bliss" policy. Commenters challenged the Agency position on the basis that these pollutants fail to identify potential long term toxicity problems. A number of commenters also criticized the use of the phrase "potential for significant discharge" in the criteria identifying Group I as unduly

vague. The minimal requirements for Group II were opposed as inadequate even to carry out the Agency's professed purpose of being able to confirm that these discharges should not be classified as Group I. Commenters claimed that with no quantified discharge data required it would not be possible to assess environmental impacts.

Finally, a commenter challenged the adequacy of the record to support the Agency's classification scheme and proposed reductions in testing.

Based upon the extensive comments, EPA has reexamined the storm water point source application requirements. The Agency is persuaded that in some respects the proposal went too far in eliminating application requirements. The final rule retains a two-tiered application approach, although both the distinguishing factors and the application requirements are modified. Group I storm water point sources are any sources subject to effluent limitations guidelines or toxic pollutant effluent standards, designated by the Administrator under § 122.26(c), or located at an industrial plant or in plant associated areas. These areas include any lands immediately adjacent to an industrial plant and such areas as industrial plant yards, immediate access roads, drainage ponds, refuse piles, storage piles or areas, and material or product loading and unloading areas. Any storm water point source discharge from these areas is considered Group I, irrespective of pollutants in the discharge. The final rule does not adopt the distinction based upon pollutants that EPA proposed. Generally, because of the greater presence and prevalence of industrial material and wastes in these areas, these discharges are more likely to contain higher levels of pollutants than other storm water point sources. For example, storm water discharges covered by effluent guidelines are included in Group I since the promulgation of the guideline represents the Agency's determination that there may be pollutant problems. Areas separate from the plant's industrial activities are excluded from Group I. Thus, commercial areas, such as office buildings and their accompanying parking lots, are excluded from Group I because they are separate from the industrial plant. All Group I storm water point sources will be required to comply with the same application requirements as other industrial point sources (as outlined in § 122.21 (f) and (g)) [CPR §§ 122.4(d) and 122.53(d)] and must submit both Application Forms 1 and 2c.

All other storm water point sources will be considered Group II dischargers. Under new § 122.21(g)(10), these dischargers are exempted from the requirement to submit Form 2c and need not submit the topographic map required by Form 1 (§ 122.21(f)(7) [CPR § 122.7(d)(7)]). However, to provide permit writers with information on the discharge, Group II storm water dischargers must provide a brief narrative description of the discharge that identifies the nature of the discharge; the drainage area, including the size and nature of that area; the receiving waters; and any treatment applied to the discharge. This information is easy to obtain and should be adequate for permit writers to determine whether a source should be designated as a Group I storm water point source.

The Agency had decided to adopt the two-tiered application approach for several reasons. EPA's resources for permitting storm water point sources are limited; the Agency and States approved to administer the NPDES program are unable to issue permits to all of these dischargers at this time. However, as discussed above, these storm water discharges are point sources under the CWA, subject to permit requirements. To balance these competing concerns, the final rule will focus application requirements upon the discharges that EPA's experience and common sense indicate are relatively more significant and reduce application burdens for other sources. Group I storm water point sources are more likely to be issued permits in a timely manner and full information is therefore required. In many cases, these sources are specifically regulated by an effluent limitations guideline, such as in the Ore Mining and Dressing Point Source Category (47 FR 54598, December 3, 1982). Permit writers will generally include permit limits for storm water outfalls covered by a guideline along with the other limits in the facility's permit. Given the likely delay in permitting Group II sources, full permit application data submitted at this time would probably be stale and useless by the time resources are available to begin permit processing. When a permitting authority prepares to issue permits to these Group II sources, it can request additional, current information. To require full Form 2c information and quantitative data in advance of that time is pointless and unnecessarily burdensome.

EPA has rejected the requests to adopt or go beyond the proposal in reducing the application requirements for Group I [commenters suggested exemption from the longitude/latitude provisions in Form 2c, Item I (§ 122.21(g)(1) [CPR § 122.53(g)(1)]) or the conventionals testings in Item 5–A of that form (§ 122.21(g)(7)(i))]. These requests are inconsistent with EPA's decision that Group I storm water point sources are sufficiently significant to submit all application materials. These data will provide permit writers with adequate data to assess the storm water discharge and impose appropriate limitations.

EPA also agrees with the logic that data on toxic pollutants should be required where such pollutants are likely to be present. It is unlikely that data on these conventional pollutants will be adequate to identify the presence of such pollutants, much less to allow permit writers to establish permit limits. As in other situations, where testing for these seven pollutants is unnecessary, permittees may request a waiver under § 122.21(g)(7)(i)(B).

Several commenters requested that oil and gas production facilities be specifically designated Group II storm water sources because they are of little environmental concern. No information has been submitted which justifies this statement. In addition, EPA has concluded that the best approach to storm water discharge is to establish application requirements based upon the likelihood that pollutants of concern may be present. Therefore, proximity to industrial facilities is a major criteria for inclusion in Group I. This applies equally to oil and gas facilities as to other industrial facilities.

*c. Other provisions.* Several persons supported the proposal to allow storm water dischargers to estimate the flow of the discharges rather than reporting the average flow as now required by § 122.21(g)(3) [CPR § 122.53(d)(3)]. Since storm water generally flows intermittently, making it difficult to obtain average flow data, EPA agrees with the commenters that it is appropriate to modify the application requirements to allow flow estimation. Applicants will have to identify the rainfall event on which the estimate is based. In addition, EPA has modified the final rule in response to a comment to require storm water dischargers to indicate the method of estimation used. The modified flow reporting requirements will not reduce information necessary to issue permits or to evaluate storm water impacts.

Several commenters supported the proposal to allow permit applications for Group II storm water discharges to be signed by a duly authorized

representative of the person or position identified in § 122.22(b). Since these discharges are generally less complex than other storm water discharges, we agree that it is appropriate to modify the signatory requirements. To relieve Group II storm water dischargers of application burdens further, today's final rule is modified as proposed. No commenters opposed the proposal.

Commenters also suggested that EPA extend the revised signatory requirements to Group I dischargers as well as Group II's. EPA does not agree that such extension is appropriate. Group I dischargers are subject to different, more detailed application requirements. Given the more serious nature of the application, it is appropriate to obtain higher level corporate involvement in the application process so as to ensure corporate responsibility.

*5. EPA action.* EPA is committed to a workable and environmentally sound approach to the control of storm water discharges, recognizing both the strengths and the limitations of the NPDES permit and non-point source programs. Today the Agency is promulgating a clear definition of storm water point sources as those which are located in urbanized, industrial, commercial areas, or are designated by the Director. It is also promulgating a two-tier application system which will enable permitting agencies to gather sufficient data to set priorities for storm water permitting and minimize the burden on regulated facilities.

EPA has retained the scope of the existing regulation defining which dischargers are point sources and are thus required to obtain a permit. The final rule defines a storm water point source as a conveyance or system of conveyances primarily used for collecting and conveying storm water runoff which is located in an urbanized area as designated by the Bureau of the Census or which discharges runoff from industrial or commercial facilities or areas or which is designated as a storm water point source by the Director. EPA has deleted the term "contaminated" as vague and confusing. In essence, the regulations will consider as point sources all storm water discharges located in urbanized commercial, or industrial areas regardless of the amount or type of pollutants they contain. EPA has adopted this approach for two reasons. First, the Agency has no information to indicate that currently regulated storm water discharges are not contributors of pollutants subject to regulation as point sources. To the contrary, preliminary analysis of data from the National Urban Runoff Program indicates that such discharges generally contain pollutants of concern, such as toxic pollutants and others, and may be best controlled under the NPDES program. Second, there is no reason to extend the current definition, since the Agency's analysis of data has not indicated that sources excluded from classification as point sources under the existing regulations are contributors of pollutants of concern that should be covered by NPDES permits.

Storm water point sources will be required to submit application information to enable permit writers to set priorities for permit issuance and to establish adequate permit conditions. All storm water discharges coming in contact with plant associated areas (as defined in the regulation) will be required to submit application form 1 and form 2c, as will storm water discharges regulated by an effluent limitation guideline or effluent standard. In addition, any other storm water discharges may be required by the Director to submit complete applications. These discharges will be classified as Group I storm water point sources. All other storm water discharges (Group II) will be exempted from the requirements of § 122.21(g) [Form 2c] and will only be required to submit Form 1 and a brief discription of type and extent of area drained and any effluent treatment. As described above, the Director may require other information on a case-by-case basis.

As part of this rulemaking, the Agency is also revoking the non-enforcement letter issued as part of the Settlement Agreement. That letter stated that EPA would not take enforcement actions against certain storm water dischargers for failure to have a permit so long as a permit application is filed within six months of promulgation of final rules or of designation as a storm water discharge. Within six months of the effective date of this regulation all Group I storm water dischargers which have not already submitted applications are required to submit complete NPDES applications, including both Form 1 and Form 2c; all Group II storm water discharges must submit only Form 1.

The Agency is promulgating as final rules two of the proposed changes. The requirement that permit applicants submit flow data is modified for storm water dischargers by amending § 122.21(g)(10)(ii) to allow such dischargers to estimate the flow if they identify the storm water event and method of estimation upon which the estimate is based. The Agency has also modified the application signatory requirements for storm water dischargers to allow applications for Group II storm water dischargers to be signed by a duly authorized representative of the person or position identified in § 122.22(a) as responsible for signing applications.

### C. Construction Prohibition (40 CFR 122.29(c)(4), (c)(5)[CPR § 122.66(c)(4), (c)(5)])

*1. Existing rules.* EPA's issuance of an NPDES permit to a new source is subject to the National Environmental Policy Act of 1969 (NEPA). Section 511(c)(1) of the Clean Water Act states that "Except for * * * the issuance of a permit under section 402 of this Act for the discharge of any pollutant by a new source as defined in section 306 of this Act, no action of the Administrator taken pursuant to this Act shall be deemed a major Federal action significantly affecting the quality of the human environment within the meaning of [NEPA]." Compliance with NEPA may involve the preparation of an Environmental Impact Statement (EIS) if the issuance is determined to be a major federal action significantly affecting the environment. As is discussed elsewhere in today's preamble, EPA has the authority to impose permit conditions, including non-water quality related conditions, or deny a permit based upon the EIS (see discussion in Part F., below).

EPA has implemented the requirements of section 511(c)(1) through several provisions of the NPDES regulations. Several sections of the regulations authorize the imposition of EIS-related conditions in NPDES permits, or the denial of permits based upon the EIS. (See §§ 122.7(g) [CPR 122.12(g)], 122.29(c)(3) [CPR 122.66(c)(3)], and 122.44(d)(9) [CFR 122.62(d)(9)] as discussed below.) In addition, in accordance with a long-standing Agency policy, § 122.29(c)(4) generally prohibits on-site construction of a new source for which an EIS is required until after final Agency action in issuing an NPDES permit that incorporates EIS-related requirements. Section 122.29(c)(5) requires an applicant to notify the Regional Administrator if the applicant commences construction in violation of this prohibition.

The "ban" on pre-permit construction of a new source is far from absolute. The regulations allow construction to commence prior to final permit issuance if the applicant executes a legally binding written agreement to comply with all EIS-related conditions. In addition, the Regional Administrator has discretion to allow pre-permit

construction to commence if he determines that it will not cause significant or irreversible adverse environmental impacts. In exercising his discretion, the Regional Administrator may, for example, allow pre-permit construction after reaching agreement with the applicant on any appropriate mitigative measures. Regional Administrators have used this authority to allow construction prior to permit issuance in a number of instances. Thus, the pre-permit construction ban does not actually bar construction where there are appropriate safeguards to protect against environmental harm. In addition, although construction in violation of the ban is a cause for denial of a new source permit application, denial is not required. A decision to deny a permit application based on violation of the construction ban will depend upon the Agency's evaluation of all factors, including the degree of environmental harm and mitigating measures taken by the applicant.

EPA established the pre-permit construction ban to ensure that it could fulfill its obligations under NEPA in issuing new source permits. EPA has relied upon the pre-permit construction ban to ensure that its statutorily required NEPA review had substantive meaning. Because important issues in many NEPA reviews are facility siting and construction-related impacts, if review takes place after construction has been commenced or completed, the review may be meaningless as to these issues. These impacts could be adequately considered during or after construction only if the significant expenditures of the applicant are ignored or if restoration of the environment was physically possible. Because this would be difficult, undesirable, and perhaps impracticable, EPA has used the pre-permit construction ban, along with the discretionary waiver, to ensure review is completed prior to construction, unless appropriate conditions can be imposed.

The Agency has taken the position, since 1976, the EPA has authority to prohibit construction of a new source prior to issuance of a permit containing EIS-related conditions. (See General Counsel Opinion No. 76–18, September 23, 1976; the General Counsel concluded that: "Congress could not have intended that [the NEPA review] be a hollow one or one of extremely limited value. The case law that has developed under NEPA is clear in requiring an agency to consider all of the reasonable alternatives to its proposed action * * *. The only way the Administrator can meaningfully consider [facility siting alternatives] in an NPDES proceeding is to perform his evaluation prior to the construction of the facility." (See also former 40 CFR § 6.906, 42 FR 2454, January 11, 1977). Pre-permit construction was expressly prohibited in both the June 7, 1979 NPDES regulations (§ 122.47(c), 44 FR 32854) and the May 19, 1980 Consolidated Permit Regulations (§ 122.66(c), 45 FR 33290).

*2. Proposed rule.* Industry litigants challenged EPA's authority to impose the pre-permit construction ban. They argued that the ban would delay construction of new sources, particularly since any administrative hearings on the permit must also be completed prior to construction. Industry also stated that the pre-permit construction ban would create inconsistencies between EPA and approved States that do not have State laws comparable to this Federal requirement. In response to these concerns, EPA proposed to eliminate the pre-permit construction ban and allow on-site construction to commence prior to permit issuance without approval by EPA or imposition of NEPA-related conditions. However, EPA noted that in performing the balance of costs and benefits required by NEPA, EPA would not consider any costs "which might be incurred by the applicant in restoring the site or in altering construction plans" no matter how substantial these costs might be. (See proposed § 122.66(c)(4), 45 FR 52091, Nov. 18, 1982.) Industry would commence construction before permit issuance entirely at its own risk, and EPA would issue, deny, or condition the permit based upon the NEPA review as if no construction had commenced. EPA's proposal was based in part on the fact that the CWA explicitly requires that EPA regulate discharges, not the construction of facilities that may discharge. Consistent with deleting the pre-permit construction ban, EPA also proposed to delete the requirement that applicants give notice of construction prior to permit issuance (§ 122.29(c)(5)).

*3. Comments and responses.* A number of commenters addressed the legality of the pre-permit construction ban. Several environmental groups stated that the proposed rule would unlawfully curtail EPA's opportunity to exercise its NEPA responsibilities and would violate NEPA, since an Agency may not take action that would foreclose reasonable alternatives to the proposed action, have significant adverse effects on the environment, or unfairly prejudice future decisions. One environmental group added that since site selection is frequently a major issue, serious and avoidable damage could result from the elimination of the pre-permit construction prohibition. Industry commenters supported the proposal, and alleged that EPA had no authority to impose the pre-permit construction ban since the CWA regulates discharges, not construction. Several argued that since a permit is still a prerequisite to discharge, EPA can carry out its obligations prior to pollutant discharge. Others argued that private facility construction is not a Federal action subject to NEPA. Industry comments also addressed the discriminatory impact of the pre-permit construction ban and its potential to delay construction activities.

Upon consideration of all the comments and a reexamination of the statute and case law, the Administrator has determined that the pre-permit construction ban is authorized by both the CWA and NEPA and that it is the most effective mechanism to enable EPA to carry out its obligation under section 511(c)(1) of the CWA. While the CWA clearly requires EPA to regulate discharges of pollutants, section 511(c)(1) also requires EPA to comply with NEPA in the issuance of NPDES permits to new sources. Under section 501(a), the Administrator is given authority to promulgate such regulations as are necessary to carry out his functions under the Act. In addition, NEPA clearly supplements the factors which EPA must consider in its decisionmaking and authorizes the Agency to take action based on its evaluation. E.g., *United States* v. *King Fisher Marine Service*, 640 F. 2d 522, 523 (5th Cir. 1981, *Calvert Cliffs Coordinating Committee*, v. *AEC*, 449 F. 2d 1109, 1115, 1128 (D.C. Cir. 1973).

EPA believes it can more effectively carry out its NEPA review if construction has not yet commenced, unless the Regional Administrator exercises his authority to allow construction to proceed prior to completion of an EIS. (The discretionary waiver provides needed flexibility to assure that construction is not unduly delayed where the review is not likely to involve irreparable harm to the environment.) A construction ban is necessary to ensure that NEPA's requirement for a comprehensive evaluation of all environmental effects of a project is not frustrated.

In order to do a comprehensive review as envisioned by NEPA, EPA must consider all reasonable alternatives to the proposed action. Once extensive on-site construction work has begun, some alternatives to the proposed action may be foreclosed, thus reducing the value of that review. One alternative to be

evaluated is whether the environment at the specific site should be altered by the proposed construction. Even where construction is appropriate, the manner and timing of construction may be legitimate factors for consideration. Options affecting significant environmental matters such as land use, aesthetics, historic preservation, and air quality might also be precluded to the extent construction is allowed to proceed. To allow construction to proceed prior to completion of an EIS could limit the Administrator's alternatives for action. The cost of remedial measures and site restoration is incalculable once irreparable alterations have already taken place. Even in circumstances where remedial measures or relocation to another site may be physically possible, it would be extremely difficult, if not impossible, for EPA to require this where the applicant has made significant capital investments in the project. EPA would also have to consider delays in the commencement of operation that would result if EPA made a permit decision that was inconsistent with the construction under way. EPA would find it difficult to ignore these factors in making its permit decision, especially since they would put the equities on the applicant's side. These considerations do not enter into the permitting process if the NEPA review and permit issuance is completed prior to construction.

As one commenter pointed out, the pre-permit construction ban is also consistent with the Council on Environmental Quality NEPA regulations (40 CFR Part 1506). These regulations establish general criteria that Agencies should follow in conducting NEPA reviews. Section 1506.1(a) of the NEPA regulations states that until an Agency issues a record of decision (including an EIS), no action should be taken which would limit the choice of reasonable alternatives or have an adverse environmental impact. The pre-permit construction ban ensures that EPA follows these guidelines.

EPA recognizes that all uncertainties for permit applicants are not eliminated under the existing regulations, since even if the Regional Administrator allows pre-permit construction, there is no guarantee that the final permit will be consistent with that construction. However, under the scheme in the existing regulations it is more likely that EPA and the applicant can consider the possible impacts of the construction prior to its commencement and can better coordinate the construction with the probable EIS outcome. These agreements will help avoid delays in operation that may result if there is no agreement and EPA subsequently makes a decision that is inconsistent with construction.

Several commenters stated the pre-permit construction ban would cause delays. Discussions with EPA Regional Offices, however, identified only a few instances in which applicants claimed that the ban actually resulted in construction delay. In some of these cases no actual delay occurred since the Regional Administrator exercised his discretionary waiver of the ban to allow construction to proceed. Very few facilities should have actual construction delays due to the construction ban. Moreover, most new sources for which an EIS would be prepared are large; there is substantial "lead time" between the planning and the construction of the facility that would allow EIS completion and permit issuance. Alternatively, the applicant could begin construction after entering into a binding legal agreement with the Regional Administrator, committing to meet certain conditions as needed to assure environmental protection. It is EPA's experience that this process provides adequate flexibility to avoid inappropriate results in specific cases.

EPA agrees with commenters who stated that private facility construction is not a Federal action. However, the CWA recognizes EPA's issuance of an NPDES permit to the facility as the Federal action which subjects it to NEPA. Construction of a discharge source generally proceeds in reliance on future Federal action: the issuance of an NPDES permit which is clearly within the Agency's jurisdiction. Without the permit the source would be unable to operate as intended. Thus, EPA's pre-permit construction review is not an attempt to control private activity per se, nor to expand the Agency's organic jurisdiction, but rather to protect the Agency's jurisdiction by preserving an unaltered balance of cost and benefit factors, as envisioned by NEPA.

In response to comments about the discriminatory impact of the pre-permit construction ban, there are at least six approved NPDES States which have State legal authorities comparable to the EPA pre-permit construction ban. Thus, contrary to the comment that the pre-permit construction ban applies only in States not approved to administer the NPDES program, construction is prohibited prior to final consideration of the environmental review in some cases where EPA is not the permitting authority. Even though there is some inconsistency since all States do not have a pre-permit construction ban, this is a natural result of the variation among State laws and would not provide sufficient justification to modify a requirement of federal law necessary to carry out EPA's independent statutory responsibilities. There would be some difference between States regardless of what action EPA takes on this regulation.

*4. EPA action.* In light of the comments, and EPA's reevaluation of legal authorities related to the duty to comply with NEPA, the Administrator has determined that retention of the prepermit construction ban and the notice of construction prior to permit issuance is appropriate. In conducting a review under NEPA, EPA must ensure that all results of that review are considered.

Moreover, the proposal would have required EPA to ignore the costs of prior construction or site restoration. As we discuss above, such a position would be very difficult to carry out in practice and would be inconsistent with the normal Agency practice, which is to consider all relevant facts available to the decisionmaker prior to final action. The decisionmaker should not ignore substantial capital expenditures and possible severe adverse economic impacts when determining whether to issue a permit. Accordingly, after a full evaluation, EPA has determined, with one exception, not to modify the existing rules on this issue.

EPA is making one change from the proposal to clarify that violation of the ban is grounds for denial of the permit. Section 122.29(c)(5) already implies that permits may be denied due to on-site construction. However, we are modifying that provision to make it clear that EPA considers violation of the construction ban to be grounds for permit denial. Consistent with existing policy, EPA will consider all factors relating to the facility in making its permit decision.

**D. Anti-backsliding (40 CFR 122.44, 122.62 [CPR §§ 122.15, 122.62])**

*1. Existing rules.* The Clean Water Act controls the discharge of pollutants through the application of technology-based effluent limitations or more stringent water quality-based standards. All existing dischargers were required to comply with effluent limitations based upon the best practicable control technology currently available (BPT) by July 1, 1977, under section 301(b)(1) of the Clean Water Act (CWA). By July 1, 1984, dischargers must comply with limitations reflecting the best available technology economically achievable (BAT), or in the case of "conventional"

pollutants, the best conventional pollutant control technology (BCT), under section 301(b)(2). This scheme of imposing increasingly stringent pollution control requirements illustrates the Act's national goal of encouraging reasonable further progress towards eliminating the discharge of all pollutants. Section 101(a)(1).

EPA is directed to implement technology-based requirements primarily through the development of national effluent limitation guidelines (guidelines) for categories of point source discharges. In the absence of applicable guidelines, NPDES permits are issued on a case-by-case basis under section 402(a)(1) of the CWA, establishing effluent limitations based on the permit writer's best professional judgment (BPJ) of what constitutes the appropriate technology requirement (BPT, BAT, or BCT). In developing these BPJ limitations, permit writers must consider the same factors (set out in section 304(b) of the CWA) that would be used in the development of an effluent limitation guideline.

In order to implement the Act's goal of continued further progress towards eliminating pollutant discharges EPA established an "anti-backsliding" policy reflected in the NPDES regulations at 40 CFR 122.44(1) [CPR § 122.62(1)]. See *U.S. Steel* v. *Train* 556 F.2d 822, 842 (7th Cir. 1977). This provision prohibited the reissuance of an NPDES permit with limitations, standards, and conditions less stringent than those in the previous permit unless the circumstances on which the previous permit had been issued had materially and substantially changed and constituted cause for permit modification or revocation. With respect to BPJ permit limitations which were more stringent than subsequently promulgated effluent limitation guidelines, "backsliding" was prohibited, except in limited circumstances set forth in the regulations.

*2. Proposed changes.* Industry litigants questioned EPA's authority to impose BPJ technology-based permit limitations more stringent than effluent limitation guidelines. They asserted that once promulgated, the limitations established by a guideline should replace case-by-case permit limitations. They also considered the anti-backsliding policy inequitable, arguing that permittees who had accepted BPJ limitations developed prior to guideline limitations are required to meet more stringent control requirements.

EPA disagreed with the challenge to the legality of the policy. However, in response to the equity concerns, EPA proposed to eliminate its anti-backsliding policy for BPJ permits where it subsequently promulgates an applicable effluent limitation guideline with limitations less stringent than those imposed in the permit. Under the proposal, EPA would, upon the request of the permittee, be required to modify EPA-issued BPJ permits to reflect the less stringent guideline limitations. Although States were free to provide similar relief, no mandatory obligation to modify State-issued BPJ permits to reflect less stringent guideline requirements was proposed, since Section 510 of the CWA authorizes States to impose more stringent requirements. EPA also proposed to apply the new policy to existing permits during their terms by adding a new cause for permit modification consistent with the above approach.

In explaining its proposed abandonment of the "antibacksliding policy", EPA stated that the national effluent limitation guidelines should be applied equally to all dischargers, rather than penalizing, or placing at a competitive disadvantage, those companies within an industry that had received a BPJ permit before guidelines promulgation. The revised policy would also facilitate issuance of second round BPJ permits that might otherwise be challenged in evidentiary hearings.

*3. Comments and response.* Many commenters addressed the legality of the antibacksliding policy. Supporters of the proposal stated that EPA had no authority to impose limitations, standards, or conditions more stringent than those in applicable law and regulations. They reasoned that after an effluent limitation guideline is promulgated, EPA must include limitations based upon that guideline in permits, in lieu of previously established more stringent case-by-case permit limitations.

Opposing commenters stated that deletion of the antibacksliding policy was inconsistent with the statutorily prescribed goal of continued further progress toward attaining the Act's goal of fishable/swimmable waters. Commenters also argued that the deletion would violate the individual permit process required by section 402(a)(1) by allowing case-by-case limitations to be relaxed even where the discharger can meet the limits at acceptable cost, where the permittee has exhausted or waived its opportunity to challenge those limits, or where the discharger already has achieved those limits. Commenters, focusing on relaxation of BPJ permits based upon BPT, stated that the BPJ permits represented the Agency's determination of BPT and therefore, BAT cannot be less stringent. However, under the proposal this could be possible if BAT guidelines were less stringent than previously established BPJ limitations.

It is EPA's position that the CWA provides the Administrator with the authority to prohibit backsliding from a case-by-case permit when a guideline is subsequently promulgated. While the CWA does not explicitly establish an antibacksliding requirement, such a requirement is a logical outgrowth of the CWA's requirements and goals. Effluent limitation guidelines are calculated for industrial categories, and represent the minimum limitations that each facility within the industry should be capable of attaining if it installs the appropriate control technology. Guidelines are generally calculated with a 99% confidence level. Therefore, if a discharger exceeds the effluent limitations established by the guideline regulation, there is a 99% certainty that it was caused by discharger error rather than statistical variation. To achieve this certainty, the limitations in an effluent guideline must be established at a level that all dischargers within the industrial category can meet after the installation of pollution control equipment. Although many dischargers should be able to attain more stringent limitations, this approach to guideline development ensures that the standard can be achieved by all facilities. It is well established that EPA has authority to set technology-based limitations required by section 301 of the CWA through industry-wide regulations, provided that limited allowance is made for variation in industrial plants. *E. I. duPont de Nemours and Co.* v. *Train* 430 U.S. 112, 97 S.Ct. 965, 975 (1977).

In the absence of guidelines, EPA has the authority to establish permit limitations on a case-by-case or BPJ basis under section 402(a)(1). In issuing a BPJ permit, permit writers must consider all of the statutory factors that pertain to the promulgation of a guideline (whether BPT, BAT, or BCT). (See discussion of the Agency's BPJ authority in section F of the preamble.) When EPA issues a BPJ permit, it establishes the Agency's determination of the appropriate technology-based limitations for the facility. See *U.S. Steel Corp.* v. *Train, supra.* Moreover, since it is calculated on a case-by-case basis, a BPJ determination can be tailored to the relevant circumstances and capabilities of the permittee and thereby inherently incorporates any necessary allowance for variations in individual plants. It would be inconsistent with that process to replace such limitations with less precisely calculated limitations. EPA's

subsequent issuance of effluent limitations guidelines does not invalidate the detailed BPJ determination of BPT or BAT/BCT made at the time of permit issuance. To adopt the policy that a subsequently issued less stringent effluent limitation guideline should replace BPJ established permit limits would cast an undeserved pall of uncertainty on BPJ permits. Such a policy could have a chilling effect on the issuance of permits in advance of guideline promulgation since the possibility would exist of a burdensome permit modification process.

A prohibition on backsliding for BPJ permits is also consistent with reasonable further progress towards controlling pollutant discharges. If a BPJ permit has been issued, a modification (or reissuance) to reflect subsequently promulgated less stringent guidelines would be inconsistent with the section 301(b)(2)(A) requirement that BAT represent reasonable further progress towards achieving the goals of the Act. Only in limited circumstances where it is demonstrated that the original BPJ limitations cannot technically be achieved despite all good faith efforts, might some allowance be legitimate. EPA has provided corrective measures for dealing with such situations in its existing regulations.

In relation to this, however, EPA does not completely agree with the commenter who stated that it was impermissible to allow backsliding where permittees had met their limits, could meet the limits at acceptable cost, or had waived or exhausted their opportunity to challenge their permits. Although backsliding, in general, is inconsistent with the Act for permittees who can or are meeting permit limitations, the anti-backsliding provision should not limit the Director when the previous case-by-case limitations prove to be an incorrect assessment of the discharger's capabilities. The regulations, therefore, create two exceptions from the policy. Permittees may obtain less stringent limitations when, despite installation and proper operation and maintenance of the necessary treatment system, they are unable to meet a BPJ permit. (§ 122.44(1)(2)(i) [CPR § 122.62(1)(2)(i)].) Today's rulemaking will also allow permits to be modified during their term in these cases. Additionally, permittees that can only meet their BPJ limitations at unreasonable costs should be able to obtain less stringent limitations. Therefore, today's regulation provides relief to a permittee that can meet its current permit effluent limitations only with operation and maintenance costs wholly out of proportion to those of average facilities covered by a subsequent guideline for the category. For dischargers with permits based upon guidelines, EPA already allows relief if the removal costs are wholly disproportionate from those considered in developing the guideline. EPA will now allow qualifying facilities to request permit modification (or reissuance) with less stringent limitations under a similar standard although the permit may not be less stringent than the subsequent guideline. The final rules thus create a new cause for permit modification. In light of this, the status of the permit and whether challenges to it have been exhausted are not appropriate considerations. However, if the facility is able to meet its BPJ limits with reasonable costs, it is consistent with the case-by-case process to require the permittee to continue to achieve those limits.

Several commenters argued that the anti-backsliding policy was unfair to permittees that accept BPJ permits and that these permittees should not be penalized. These commenters pointed out that permittees that contest case-by-case permits may be rewarded. Another commenter countered that EPA had not demonstrated that the anti-backsliding policy would place BPJ permittees at a competitive disadvantage.

It is possible that some case-by-case permittees will attempt to delay the permitting process in the hope that they will obtain less stringent limitations. However, as we explained above, a BPJ permit represents the Agency's determination of the appropriate technology-based limitations applicable to an individual facility. It would be inconsistent with the goals of the Act for the Agency to reverse that decision solely because a permittee may try to delay a permit process in hopes of achieving a more favorable result. In addition, the Agency received no specific data from commenters in support of the allegation that the anti-backsliding policy created a competitive disadvantage.

Commenters agreed with EPA's statement in the proposal that the anti-backsliding policy could result in challenges to second round NPDES permits. EPA acknowledges that it cited this concern in the November 18, 1982 preamble as support for the proposed elimination of the anti-backsliding policy. At the time, EPA expected to issue many of the second round permits on a case-by-case basis and anticipated that many would be challenged. Since then, a great deal of progress has been made in promulgating effluent limitations guidelines. In addition, EPA's second round industrial permit issuance policy assigns highest priority to permits that will be based on water quality standards more stringent than technology standards. In other cases, if promulgation of a guideline is expected, EPA will generally defer permit issuance rather than issue a BPJ permit. Thus, it now appears that far fewer permit challenges will result from the anti-backsliding policy than had been anticipated.

Two commenters pointed out that the Agency's retention of § 122.44(l)(2) [CPR § 122.62(l)(2)] (which sets out specific instances under which BPJ permits may be reissued with less stringent limitations) was inconsistent with the proposed revision and ought to be deleted. EPA agrees with the commenters that the retention of this language was inconsistent with the proposal. However, since today's final rule does not eliminate the anti-backsliding policy as it applies to BPJ permits, it is unnecessary to delete § 122.44(l)(2).

One commenter stated that since the proposed rule appeared in § 122.62(a) [CPR § 122.15(a)] "Cause for Permit Modification", we should clarify that the change would also apply to permit renewal and revocation and reissuance. The commenter's question reflects a misunderstanding of § 122.62(a). Section 122.62(a) states that if the permittee agrees, each of the causes for permit modification also constitutes cause for permit revocation and reissuance. The proposal would also have applied to renewal through § 122.44(l)(1) which states that permits may be renewed with less stringent limitations if there is cause for permit modification under § 122.62.

A single commenter stated that dischargers covered by revised water quality standards should also be able to obtain less stringent limitations at reissuance. The existing NPDES regulations already contain provisions that allow this change. Section 122.62(a)(3) allows permit modification if the permit is based upon a water quality standard or promulgated effluent limitation guideline and that standard or guideline is made less stringent. This also applies to reissuance through § 122.44(l).

Another commenter stated that we should clarify that the term "effluent limitations guidelines" in the proposed rule and in § 122.62(a)(3) includes New Source Performance Standards (NSPS). Thus, if EPA wrote a permit based upon an NSPS that was subsequently modified or revised, the permittee could

request permit modification to obtain less stringent limitations. The commenter further argued that since the permittee would no longer be a new source, EPA could not apply NSPS to these permittees, but would be required to include BAT conditions.

The suggested interpretation of § 122.62(a)(3) and the proposed rule is inconsistent with the existing regulations. The NPDES regulations define the term "effluent limitations guidelines" as regulations published under section 304(b) of the CWA. (See § 122.2 [CPR § 122.3].) Effluent limitations guidelines thus include BAT, BPT, and BCT guidelines, but not NSPS which are promulgated under section 306 of the CWA. The reference to "standards" in § 122.62(a) is clearly intended to refer to water quality standards and not NSPS. Thus, by the terms of this regulation, sources covered by an NSPS are subject to the Agency's current anti-backsliding policy.

The regulation is supported by section 306 of the CWA which requires that NSPS reflect the greatest degree of effluent reduction determined to be achievable through the application of the best available demonstrated control technology. NSPS are only applicable to sources which are constructed after proposal or promulgation of an NSPS (see 40 CFR 122.2). This is because NSPS are intended to impose state-of-the-art technology upon new sources which are capable of constructing their facilities to meet such requirements. Limiting the circumstances by which these NSPS can be modified once imposed on a facility is consistent with Congressional intent that NSPS represent the "maximum feasible control of new sources," S. Rep No. 92–414, p. 58 (1971), Leg. Hist. 1476. See also *E. I. duPont de Nemours & Co.* v. *Train* 430 U.S. 112 (1977) (a variance procedure for NSPS is inappropriate).

Promulgation of a subsequent "new" NSPS by the Agency does not justify elimination of the anti-backsliding policy. It is clear under the statute that a later promulgated NSPS would not apply to "existing" new sources since the "existing" new source was constructed prior to the promulgation or proposal of the "new" NSPS. Furthermore, the promulgation of the "new" NSPS does not withdraw or revise the original standard for an "existing" new source since by its terms it only affects "new" new sources whose construction commenced after its promulgation. Thus, the commenter's statement that the promulgation of a subsequent NSPS converts the "existing" new source into an existing source subject to BAT effluent limitations is incorrect. Rather, the existing NSPS remains applicable to sources that were constructed after its promulgation but before a new NSPS is issued. Modification of permit limitations based upon the existing NSPS to reflect later promulgated NSPS would be inappropriate.

Only in a situation where the new NSPS was intended to withdraw or revise, in whole or in part, the previous NSPS because of some error or infeasibility might an exemption from the anti-backsliding be legitimate. See, for example, the recent proposed changes to the NSPS for coal mine point sources. 49 FR 19240 (May 4, 1984). However, a change to the NPDES regulations at 40 CFR 122.62(a) to modify the anti-backsliding policy to generally allow for backsliding with respect to NSPS would require reproposal to allow for public coment since the issue was not raised by the November 18, 1982 proposal. Since the Agency considers it appropriate to retain the anti-backsliding policy for NSPS, EPA is not proposing such a change.

One commenter stated that EPA cannot allow backsliding to BCT guidelines where the inital BPJ/BPT permit limitations are more stringent than the guideline limitations. This commenter misconstrues the existing regulations which now contains an exception from the anti-backsliding policy allowing BPJ permit limitations to be made less stringent to conform to a later promulgated BCT effluent limitation guideline (§ 122.44(l)(2)(iii) [CPR § 122.62(l)(2)(iii)]). EPA included this exception in the June 7, 1979 NPDES regulation, reasoning that it would only be available in a small number of cases and that it was in accord with Congressional intent that BCT, rather than BAT, represent the highest level of treatment applicable to conventional pollutants (44 FR 32864, June 7, 1979).

On reevaluation, the Agency recognizes that the BCT exception as explained in the 1979 preamble in inconsistent with the general intent of the anti-backsliding policy to prevent unwarranted "backsliding" in pollution control. EPA agrees with the commenter's statement that BCT must in all cases be at least as stringent as BPT, whether BPT is in a guideline or in a BPJ permit. Moreover, requiring permittees to maintain the level of control imposed by BPT requirements would not be contrary to Congressional intent with respect to control of conventional pollutants. Under section 301(b)(1), all dischargers are required to comply with BPT requirements by 1977. BPT is intended to be the floor for purposes of determining BCT requirements whether BPT was established by guideline promulgation or by a permit writer's best professional judgement.

Due to the inconsistency in our current regulations, EPA is considering revising the BCT exception to make it consistent with the rest of the anti-backsliding policy. The Agency is currently working on a BCT methodology and has not yet promulgated any BCT guidelines. Additionally, it is unclear whether there are any BPJ permits more stringent than BPT or BCT guidelines that will present a real backsliding issue. Therefore, the Agency will assess the need to correct the anti-backsliding policy in conjunction with issuance of a final BCT methodology. If BCT guidelines are likely to allow backsliding, EPA will propose a revision to correct the anti-backsliding regulation at that time.

Finally, one commenter supported the proposal on the grounds that it would allow EPA to correct previous errors. This provision is not intended to provide general authorization to correct previous errors. EPA already has authority to correct BPJ permit limitations when they are unachievable. As noted above, existing § 122.44(l)(2)(i) allows the reissuance of permits with less stringent limitations if permittees install and properly operate and maintain the necessary BPJ limits. Elsewhere in this rulemaking, we are extenting this policy to apply to *modification* of BPJ permits. Under today's revision, the permitting authority will also be able to modify (or reissue with less stringent limitations) BPJ permits upon promulgation of subsequent guidelines when they can only be achieved with costs wholly disproportionate to those considered in the guidelines, although the revised limits may not be less stringent than the guideline.

*4. EPA action.* Based upon EPA's review of the comments and the requirements of the CWA, the Agency has decided to retain the current anti-backsliding policy with one exception. The regulation will now allow BPJ permits to be made less stringent if the permittee can demonstrate that its removal costs are wholly disproportionate to those considered in a subsequently promulgated effluent guideline. This demonstration should be equivalent to the similar showing in variance requests from guidelines-based permit limitations (see § 125.31(b)(3)).

Generally, the BPJ permit limitations are based upon technology that is widely known and not different from that considered in guideline development. Permit writers usually

know the approximate removal costs at the time the limitations are established. However, in some cases, technology may be installed that requires unexpected and inordinate operation and maintenance costs to meet the guideline. In these cases, we will revaluate the previous determination and allow the permit to be modified to reflect removal costs that are not wholly disproportionate to those on which the guideline is based (although in no event may the limitations be made less stringent than the guideline without a variance).

EPA would like to clarify one final point on the new information exception to the anti-backsliding policy in the existing regulations. For purposes of implementing the anti-backsliding provision in § 122.44(l) for a reissued permit, where limitations in the expiring permit were based on water quality standards, "information" under § 122.62(a)(2) may include alternative grounds (including necessary methodology; mathematical parameters, and other assumptions) for translating water quality standards into water quality-based limitations.

**E. Disposal to Wells, POTW's, or by Land Application (40 CFR 122.50 [CPR § 122.65])**

*1. Existing rules.* The existing regulation sets forth a formula for adjusting mass-based permit effluent limitations for those dischargers that do not dispose of all their wastes to waters of the United States. The purpose of the formula is to assure that if part of a discharger's total process wastewater flow is diverted to wells, land application or POTWs, the remaining wastes discharged to surface waters are subject to technology-based requirements notwithstanding the diversion. Mass-based limitations are adjusted proportionally to the percentage of the wastewater disposed into a well, a POTW, or by land application. Thus technology-based effluent limitations cannot be met merely by diverting most of the wastestream by one of these three methods.

The existing regulation does not limit or prevent a discharger from disposing of part or all of its wastewater to a well, by land application or to a POTW. That decision is clearly within the discretion of the discharger. The provision simply recognizes that the NPDES permit program of the CWA focuses on control of that waste *actually* discharged to waters of the United States. Therefore, limitations calculated upon the assumption that a facility's entire wastewater flow would be discharged to waters of the United States must be adjusted to reflect the fact that only a portion of it is in fact being discharged. This technical adjustment is accomplished through use of the formula in the existing regulation. The regulation does not regulate, directly or indirectly, the wastewater that is diverted. No limits are placed on the amount of wastewater that may be diverted, nor upon how that waste is treated or disposed of. Generally, such activities are outside the scope of the NPDES program.

The existing regulations also provide that, if a discharge to a well, POTW, or by land application "changes the character or treatability" of the pollutants being discharged to receiving waters, the effluent limitation can be made more stringent than required by application of the adjustment formula established in the regulations. This provision was originally included in response to comenters' concerns that a strict application of the formula would otherwise allow a discharger to inject concentrated wastes into a well, to a POTW, or by land application and then discharge relatively dilute wastes to surface water with little or no treatment.

*2. Proposed changes.* Industry litigants complained that the adjustment formula in the regulation unlawfully and unfairly discriminated against some forms of treatment in favor of others. They claimed that their diversion of wastewater to land application, a POTW or a well was, in fact, treatment of that waste for purposes of the Clean Water Act and that therefore no adjustment of their permit limits was necessary or appropriate. Industry supported this assertion by contending that since mass-based permit limits are based on a discharger's level of production and not the volume of wastewater discharged, reduced flow was not grounds for different permit limits. The litigants further argued that the adjustment formula was flawed. They alleged that it assumes pollutant load to be uniform over all flow rates and treatment plant efficiency to be linear; litigants opined that treatment plant efficiency might decline when flow is reduced.

In the settlement with industry litigants, EPA agreed to propose their approach for public comment.

Consistent with that agreement, the proposal would amend the regulations to recognize land application and well disposal as forms of treatment, under the NPDES program, that prevent wastes from reaching waters of the U.S. Therefore, technology-based limitations would not be adjusted if part of the wastestream was disposed of in a well or by land application. The remaining wastes directly discharged would be allowed the full wasteload limitation.

The proposal, however, retained the adjustment formula for industries which discharge a portion of their wastes into POTWs, since pollutants from a POTW *will* (indirectly) be discharged into waters of the U.S. However, the adjusted effluent limitation could be further adjusted under the proposal if the effluent limitations yielded by the formula would require a greater degree of effluent reduction (taking into account both reduction of the POTW and reduction at the permittee's facility) than would have been required if the industry has treated and discharged all its wastes directly to the receiving waters.

Furthermore, the proposal removed the "change the character or treatability" provision which would have allowed the effluent limitation to be made more stringent if the wastewaters directly discharged were not representative of the total waste flow. This provision would have been superfluous under the proposal.

*3. Comments and responses.* Several commenters supported the proposed rule and reiterated litigant contentions that well injection and land application are forms of treatment and that the existing regulation unlawfully discriminated against such forms of treatment. One commenter believed EPA should not be concerned about the impacts of diverted wastewater because other programs such as the UIC, pretreatment, and RCRA programs should adequately protect the environment. Other commenters objected to well injection and land application being considered forms of treatment. They stated that the overall effect of such an interpretation would be an increase of pollutant discharges to the waters of the U.S. and to the environment. These commenters pointed out that both disposal into wells and land application may ultimately result in contamination of ground and surface waters. One commenter stated that the proposal could lead to the situation where a facility discharged all but the guideline amounts to land or wells and then discharged the remainder to surface waters, untreated. Similarly, another commenter claimed that the proposal would allow a municipality to discharge raw sewage from a portion of its population if wastes from the remainder of its population are disposed of on land or by discharge to another municipality.

Other commenters objected to land application being considered treatment

that prevents wastes from reaching wastewaters of the U.S., since surface runoff from the application area would convey applied pollutants to receiving waters. One commenter objected to EPA's "novel" approach, stating that underground injection cannot be considered a form of treatment, and, in fact, is more properly regarded as a substitute for treatment.

After reviewing comments received and reevaluating the issues, the Agency has decided to retain the existing regulation. If all the effluent limitations guidelines and permit limitations were expressed solely in terms of concentration, there would be no need for the adjustment formula contained in the existing regulation. If a discharger sent half of his wastewater to an injection well or land application, a concentration-based limit would assure the same level of treatment of wastewater directly discharged as would have been applied to the total wastestream. However, to preclude dilution as a substitute for treatment and to encourage flow reduction (such as recycling of process water) at the industrial facility, effluent limitation guidelines are often expressed solely in terms of mass. While mass-based limits address the problems related to dilution, such limits do not similarly assure a consistent level of treatment for dischargers who reduce flow by well injection, land application, or routing to a POTW. By retaining the existing regulation, EPA ensures that the regulatory approach to both mass-based and concentration-based limits is consistent.

The policy in the existing regulation is also consistent with the development of effluent guidelines. Production-based mass limits in effluent limitations guidelines are based upon the assumption that total process flows would be directly discharged. In the guideline development process, the treatment technology is evaluated and a concentration limit determined. The concentration limit is then multiplied by the process flow per unit of production. The result of this multiplication is the mass limit per unit production. If some of the process flow is diverted, it is necessary to adjust the above calculation since the mass guideline limit is based upon the total process flow. (While flow reduction techniques may also reduce process flow to the treatment facility, there is no diversion of wastewater containing pollutants; since pollutant loads are not changed, adjustment is unnecessary.) The existing regulation makes the necessary adjustment by revising the limitation to reflect the amount of wastewater directly discharged.

Furthermore, the adjustment of mass-based permit limitations accords with the intent of the CWA. Section 402(a)(1) authorizes the Administrator to issue a permit for the "discharge of any pollutant" upon the condition that the discharge meets the requirements of, *inter alia*, section 301. It is clear from the Act that the "discharge of a pollutant," as defined in section 502(12), must comply with the technology-based standards of section 301. If part of a discharger's process wastewater is released to the environment in a manner that is not a "discharge of a pollutant," e.g., into a POTW or by land application, then it would be inappropriate to allow the discharger to escape the technology-based requirements of section 301 in the section 402 permit for the remaining flows. The existing regulation requires the same degree of treatment to the wastewater directly discharged as would have been applied to the total wastewater. As noted, this is also the same degree of treatment that would be required if EPA had included concentration-based limits. Dischargers should not be given a credit merely because EPA chose to encourage flow reduction by solely limiting pollutant mass. To give a discharger "credit" because he disposed of the rest of his wastewater into an injection well or by land application would be inconsistent with the intent of the CWA to apply technology-based limits to all discharges to waters of the U.S. The statute requires technology-based limits for "discharges of pollutants" without regard to whether all or only some process wastewater is discharged.

Waste disposal through land application and discharge to wells also presents environmental risks of an unknown dimension. Surface impoundments and water treatment lagoons that handle other than hazardous wastes are not extensively regulated by the Agency. EPA's recently completed Surface Impoundment Assessment indicates that many such facilities have the potential to and do contaminate groundwater. About 40% of municipal and industrial impoundments are located in areas with thin or permeable soils or over aquifers currently used or that could be used for drinking water. The impact of land application systems upon groundwater is not yet known, although recent information indicates some environmental threat. Also, some land application systems are designed to lead to sheet runoff to surface waters, which would be classified as a non-point source not subject to NPDES permitting. Although well injection will ultimately be regulated by the Underground Injection Control (UIC) Program, the UIC program is not yet fully implemented in most States, and requirements for some varieties of wells have not yet been specified. In light of the risks, well injection and land application should not be considered treatment for the purpose of avoiding recalculation of mass-based permit limitations, since they could ultimately result in increased release of uncontrolled pollutants to the environment. The present uncertainty and potential for harm as well as the fact that NPDES permit writers are not equipped to evaluate the effectiveness or environmental impacts of these means of disposal is another reason EPA has decided not to allow credit.

Contrary to one commenter's view, EPA does not intend or expect its action today to discourage land application or well injection where these are appropriate. Dischargers can still dispose of any part of their wastewater by land application or well disposal. The NPDES regulations are neutral and are not intended to either encourage or discourage other disposal options. If a portion of a discharger's process wastewater is disposed into a well or by land application, the proposal would have allowed the remaining wastewater to be directly discharged with the same total mass of pollutants as if *all* the wastewater were directly discharged. In some, perhaps many cases, this would mean that the discharge itself would not be treated at all. Such a result would be inconsistent with the basic technology-based approach of the CWA.

One commenter asserted that the existing regulation would, in effect, penalize a discharger for her investment in wells or in land application by requiring more stringent treatment of the wastewater actually discharged to the waters of the U.S. EPA does not agree because, as indicated above, the regulation does not require *more* stringent treatment but simply a proportionate level of treatment for the portion which is directly discharged. If a facility chooses to dispose of some wastewater by land application or other means instead of discharging it directly, that decision is most likely based on a weighing of all relevant factors, one of which is the relative costs. The Agency is not concerned with this industrial cost balancing, but rather with ensuring that *whatever* amount of wastewater the facility ultimately decides to discharge is treated to a level consistent with the CWA requirements. Consistent with this

approach, the costs of disposal into a well, POTW, or by land application will not be considered appropriate costs in determining control measures which constitute BPT, BAT or BCT in BPJ determinations.

In a similar vein, it has been asserted by a commenter that the Agency has not considered the economic achievability of complying with an effluent guideline limitation if that limitation has been adjusted to reflect reduced flow. This assertion is incorrect. The determination of economic achievability for an effluent limitations guideline also applies to the adjusted limitation.

When technology-based effluent limitations guidelines are developed, the Agency estimates the costs for investment and operation of a treatment system. If plant-specific costs are estimated, the size of the treatment system reflects the amount of the facility's wastewater. This amount of wastewater flow may reflect the facility's current flow or a reduced flow that the Agency believes can be achieved through process changes such as recycling. In either case, the costs of the treatment system reflect those that will allow the facility to comply with the effluent guideline limitation. These costs are the basis of the economic impact analysis, which is used to determine economic achievability.

If a discharger chooses to reduce wastewater flow by disposal practices such as well injection, a smaller or less extensive treatment system should be required and the end result will still be economically achievable. In fact, the discharger would likely not make such a change unless it results in cost savings. It is reasonable to assume that in exercising its discretion to select wastewater disposal practices, a facility will not choose a more costly option than is necessary. EPA should not adjust the regulations to benefit dischargers that choose a more expensive method of disposal.

Other commenters point out that the proposed rule would be unfair to dischargers tht discharge directly because a comparable degree of treatment would not be required for those using land application or an injection well. EPA agrees that in some circumstances inequities could result if a competitor were able to avoid treatment costs by disposing of part of his wastewater to a well or by land application. In addition, the proposal would lead to inequities between dischargers with concentration-based limits and those with mass-based limits, since concentration-based limits remain applicable, unchanged, even if a portion of the wastewater is land applied or injected to wells.

Another concern raised by commenters was in reference to the existing provision which provides EPA with the authority to make the limitations more stringent under Part 125, Subpart D, if discharges to wells, POTWs or by land application change the "character or treatability" of the pollutants discharged to receiving waters. One commenter pointed out that the proposal never provided a reason for omitting that provision. The proposal to provide treatment "credits" for disposal into wells, by land application and for the amount of effluent reduction at a POTW, would have eliminated the need for the "character or treatability" provision. Since EPA has decided not to proceed with the proposed approach, it is appropriate to maintain that provision.

A few commenters stated that the existing regulation assumes that the efficiency of a treatment plan is linear, but in fact the efficiency declines when process flow is reduced. Generally, EPA's experience is that efficiencies of treatment systems are linear in relation to flow. Effluent guidelines regulate large and small plants based upon a linear model; the discharge limit is based upon the size of the plant reflected by its production level and process wastewater flow. In fact, contrary to the commenters' suggestions, EPA expects that, in most instances, if the flow is reduced, the efficiency of an existing treatment plant would increase because of the greater retention time of the wastewater by the treatment facility.

However, in certain circumstances the efficiency of a treatment plant may decline when process flow is reduced. This might occur, for example, if disposal of highly concentrated wastewater to a well, POTW or by land application leaves a discharger with highly diluted wastewater to be treated. It is also possible that the situation might arise where the efficiency of a plant declines merely because the process flow is reduced. If application of the adjustment formula would lead to removal costs which would be wholly out of proportion to the removal costs considered during development of the national limits, then the discharger may be eligible for a further adjustment under Part 125, Subpart D fundamentally different factor variance procedure. For this reason, today's rulemaking clarifies that the effluent limitations may be further adjusted under Part 125, Subpart D to make them either more or less stringent if disposal to a well, POTW or by land application changes the character or treatability of the pollutants being discharged to receiving waters. This clarification should alleviate the concerns of commenters who pointed out that a reduction in flow rate may decrease efficiency or that the existing regulation assumes that pollutant loads are uniform over all flow rates.

In the case of discharges to POTWs, the proposal would have allowed effluent limitations to be adjusted if the effluent limitations yielded by the formula would require a greater degree of effluent reduction (taking into account both reduction at the POTW and at the permittee's facility) than would have been required if the industry had treated and discharged all its wastes directly to the receiving waters.

Several commenters supported the proposed approach for POTWs. Another commenter pointed out that this provision is equivalent to "removal credits" which provide a discharger into a POTW with an allowance for the treatment achieved by the POTW. However, the commenter stated that it does not have any of the detailed showings and other safeguards required under the removal credit program in 40 CFR 403.7. Consistent with the approach taken with respect to well disposal or land application, the final regulation applies mass-based guidelines to the wastewater to be directly discharged into waters of the U.S. If part of the total wastewater is disposed of elsewhere (e.g., into a POTW), it shoud be dealt with in the context of other regulatory programs. For example, discharges to POTWs must meet categorical pretreatment standards and other local limits imposed on industrial dischargers by the municipal treatment authority. Wastewater disposed into a POTW may be eligible for a removal credit under a pretreatment program and will be dealt with in that context.

*4. EPA action.* After analyzing the comments received and reevaluating our proposal, we have decided to retain our long-standing policy expressed in the existing regulation. In response to comments, however, we have clarified the regulation to allow less stringent limitations if the character or treatability of discharged wastewater is changed.

It should also be clarified that when information comes to the attention of the permitting authority concerning a discharger reducing the flow upon which a permit is based by well injection, land application or discharge to a POTW, this constitutes grounds for permit modification as new information under 40 CFR 122.62(a)(2) [CPR § 122.15(a)(2)].

**F. Best Professional Judgment (BPJ) and Draft Development Documents and Treatability Manual**

*1. Best Professional Judgment (BPJ) (40 CFR 124.56(b)(1), 125.3(c) (2), (3), 125.3(d)).*—a. *Existing rules.* Effluent limitations may be established on a case-by-case basis under section 402(a)(1) of the Clean Water Act in the absence of applicable effluent limitations guidelines, or in addition to effluent limitations guidelines if these guidelines do not control pollutants of concern or particular wastestreams at a facility. Permits containing case-by-case effluent limitations are based on a permit writer's "best professional judgment" (BPJ) and represent the appropriate statutory requirement—"best practicable control technology currently available" (BPT), "best conventional pollutant control technology currently available" (BCT), or "best available technology economically available" (BAT)—for that particular facility.

Because "BPJ" permit effluent limitations and conditions operate in the absence of, or in addition to, effluent limitations guidelines authorized under section 304(b) of the Clean Water Act, permit writers are required to apply the appropriate statutory factors in that section when imposing technology-based effluent limitations in permits on a case-by-case basis. The current regulations clearly state this obligation by requiring permit writers when writing BPJ permits to "apply the appropriate factors listed in section 304."

*b. Proposed changes.* Industry litigants were concerned that permit writers would not address these statutory factors unless expressly listed in the regulation. They were also concerned that permit writers would not explain the basis for their case-by-case determinations unless the regulation expressly required that their bases be set forth in the fact sheet required by § 124.56. EPA responded to these concerns by proposing to list the section 304(b) factors in proposed § 125.3(d) and to specifically reference the fact sheet in proposed § 125.3 (c)(2) and (c)(3). EPA also proposed a conforming revision to § 124.56(b)(1).

*c. Comments and responses.* Industry groups supported the proposed changes contending that listing the statutory factors would help ensure that permit writers follow the proper methodology in setting BPJ effluent limitations. They also claimed that requiring the fact sheet to set forth the basis for BPJ limitations would make it easier for applicants to comment on draft BPJ permits and for courts to review challenges to these permits. Two States administering the NPDES program objected to the proposal on the grounds that it would impose a burdensome requirement on the administering agency and, if followed literally, could make the fact sheet a larger document than the permit.

Sections 124.8 and 124.56 of the current NPDES regulations require permit writers to prepare a fact sheet for every draft permit for a major NPDES facility or activity. In accordance with these provisions, a fact sheet must include calculations or other necessary explanations of the derivation of specific effluent limitations and conditions, including a citation to applicable effluent limitations guidelines or where not applicable, an explanation of how alternative limits were developed. (For minor dischargers the permit writer must prepare a statement of basis (40 CFR 124.7). Although less detailed than a fact sheet, a statement of basis still requires an explanation of the derivation of the permit conditions.) States opposing the proposal apparently believed that reference to the fact sheet in proposed § 125.3 (c)(2) and (c)(3) imposed some greater burden of justification for BPJ limitations. The intent was merely to point out the requirements of §§ 124.8 and 124.56 of BPJ situations. To avoid misunderstanding, EPA has deleted the reference to the fact sheet in proposed § 125.3 (c)(2) and (c)(3) as redundant with existing §§ 124.8 and 124.56. The final regulation retains the section 304(b) statutory factors a permit writer must consider when setting technology-based effluent limitations on a case-by-case basis. Although BPJ permit writers are required to consider these factors whether or not they are listed in the regulations, the Agency agrees it is more efficient and effective to restate them in the regulations.

One commenter requested that permit writers be specifically instructed in § 125.3 to use the proposed BCT methodology (47 FR 49176 et seq., October 29, 1982) in determining BPJ–BCT effluent limitations. Since the BCT methodology has not yet been finalized, it would be inappropriate to reference it in this rulemaking. However, permittees and permit writers should be aware that once EPA establishes a BCT methodology, permit writers must apply this methodology in establishing BPJ permit limitations.

*d. EPA action.* Based on an evaluation of the comments in light of our BPJ permit experience, EPA will retain the list of statutory factors but has not adopted the fact sheet portion of the proposal.

*2. Draft Development Document and Treatability Manual (40 CFR 125.3(c)(2)).*—*a. Existing rules.* The current regulation includes EPA draft or proposed development documents or guidance in a parenthetical clause as examples of available information a permit writer must consider when making case-by-case determinations of technology-based effluent limitations.

*b. Proposed changes.* Industry parties to the settlement agreement were concerned that permit writers would do more than just *consider* development documents and guidance when writing BPJ permits. They feared that permit writers would be bound by these documents which, in their opinion, often contained faulty data. Additionally, litigants claimed that if permit writers are required to consider draft development documents and guidance, there would be no incentive for EPA to finalize effluent limitation guidelines. In response to these concerns, EPA proposed to delete the parenthetical reference to the documents in § 125.3(c)(2)(i), and stated in the preamble to the proposal that although not bound by EPA draft or proposed development documents or guidance, permit writers must consider all pertinent information, including these documents, in developing case-by-case effluent limitations.

*c. Comments and responses.* We received two comments on this issue. Both supported the proposed deletion of the parenthetical clause and stated that this change would ensure that undue weight would not be given to these documents.

*d. EPA action.* The final regulation does not contain the parenthetical clause. EPA continues to support the position taken in the preamble to the proposal that in establishing case-by-case permit limitations under section 402(a)(1) of the CWA, permit writers are not bound by EPA draft or proposed development documents or guidance. Permit writers should consider all pertinent information, including these documents, when developing case-by-case effluent limitations, just as they must consider significant comments and criticisms of the data they contain.

**G. Net/Gross Limits (40 CFR 122.45(g)) [CPR § 122.63 (g), (h)]**

*1. Existing rules.* The issue of whether and to what extent net/gross credits should be granted arises because of what appears to be a fundamental dichotomy. Industry has argued that dischargers are not responsible for removing pollutants already present in their intake water. (See *Appalachian*

*Power Co.* v. *Train*, 545 F.2d 1351, 1377 (4th Cir. 1977)). This should lead, they contend, to simple subtraction of intake pollutant values from effluent values when setting permit limits and measuring compliance. However, effluent limitations guidelines (guidelines) and other technology-based permit limitations are written on a gross basis without any such subtraction, because within a broad range of influent pollutant concentrations, treatment systems typically reduce pollutants to a certain level. Pragmatically, therefore, technology-based limits should be achievable regardless of the amount of intake pollutants. To grant a net/gross credit may give an unfair advantage to facilities with measurable levels of pollutants in their intake waters. Such facilities, by relying on intake credits, could "comply" with effluent limitations by utilizing a lower level of treatment than their competitors on cleaner streams—frequently a far lower level of treatment than that designated by EPA as BAT. Furthermore, intake pollutants rarely simply pass through a facility and all its associated intake and/or effluent treatment without some removal and/or complicated exchange of pollutants. In particular, generic pollutant parameters, such as total suspended solids or biochemical oxygen demand, frequently measure very different things in the influent and effluent. Thus, a simple subtraction of intake pollutants often does not make sense and would result in relaxing control standards in inappropriate circumstances.

The existing rule was intended to provide an allowance for intake pollutants considering the circumstances described above. Credits are available for pollutants to the extent that they are not removed by intake and effluent treatment systems. Also, to qualify for a credit, the intake water must come from the "same body of water" as that which receives the discharge. Additionally, pollutant parameters in the effluent must be physically, chemically and biologically identical to those found in the influent. These and other conditions are intended to address the problems described above and to limit the use of net credits to appropriate circumstances.

*2. Proposed changes.* Industry litigants were concerned that the restrictions in the existing rule severely limited the availability of net credits. For example, most pollutants change form in some way as they pass through a facility, and thus it is nearly impossible to provide exact physical, chemical, and biological identity between intake and effluent pollutants. EPA, for its part, was concerned that permitting authorities were overlooking the need for careful application of net credits due to the excessive complexity of the existing rule. Therefore, the proposal dropped many of the existing restrictions in an attempt to respond to both these concerns. They were replaced by a statement that net credits would be given only where necessary to meet applicable technology-based limitations. In place of the demonstration of exact equivalency of pollutant parameters in influent and effluent, three alternative demonstrations of substantial similarity were provided. The "same body of water" restriction was dropped. (See 47 FR 52080–81, November 18, 1982.) Both th existing rule and the proposal reflected the efforts of many parties to deal with many individual situations of concern. In both cases, this led to detailed and lengthy regulations and preamble discussions. The settlement agreement resulted in such a complicated proposal that EPA became concerned, after reviewing public comments on the proposal, that the proposed changes failed to simplify the net/gross provision so that it might be properly understood and implemented.

*3. Comments and responses.* The most controversial aspect of the net/gross issue was the removal of the "same body of water" restriction. Industry comments were strongly in favor of removal of this restriction while environmental groups and government organizations were strongly opposed. One government organization stated that it was aware of several instances in which contaminated groundwater was being used for non-contact cooling water and discharged to cleaner surface water without treatment. During the development of the existing rule, EPA was particularly concerned with fresh water discharge to estuaries. Several of the environmentalist and government organizations gave hypothetical examples in support of retention of the restriction. Industry commenters claimed that water quality standards were sufficient to protect receiving water while those opposed to the proposal pointed out that standards are often inadequate, especially for toxic pollutants. While EPA agrees with this latter argument, we also note that in some limited cases the same body of water restriction may not be appropriate. One example might be a case where intake waters are taken from a relatively clean tributary of a relatively dirty body of water and discharged to the latter body, possibly adjacent to where the tributary itself flows into the large body. Therefore, EPA has decided to retain the same body of water restriction but with some discretion available to the permitting authority to waive the requirement on a case-by-case basis. EPA agrees with the commenters who said that water quality standards are often inadequate since many States have not yet developed specific limitations on toxic pollutants, and hence meeting water quality standards is not alone a sufficient condition for this waiver.

One commenter stated that the proposed regulations have too many restrictions and give too much discretion to the permit writer. The commenter said industry is not responsible for removing pollutants in the intake water and that EPA should provide for simple subtraction of all intake pollutants from effluent standards. For the reason stated above, EPA cannot accept this argument. Intake pollutants do not pass through intake treatment systems, facilities, and effluent treatment systems unchanged. Thus, simple subtraction would amount to a relaxation of standards that were based on a determination of what technology can achieve, without taking into account the true removals the technology accomplishes. Another industrial commenter stated that EPA should "continue to allow a full credit * * and * * * not use a threshold test." The commenter misinterprets the current regulation which does not allow a full credit, but only a credit after consideration of removal in intake and effluent treatment systems. Today's regulation replaces that complicated calculation with a more simple approach of granting credit as needed to meet technology-based standards.

Several commenters stated that the proposal was too complex. As indicated above, EPA agrees and, in today's final rule, has attempted to simplify the regulations and preamble explanation. A State agency commented that discretion regarding net credits should be left to the permitting authority. EPA agrees that the permitting authority is best positioned to decide when net credits are appropriate and has significantly simplified the regulation and preamble to further this principle.

A commenter representing a water treatment plant supported the proposed changes to the net/gross rules and argued that raw water clarifier sludge and filter backwash should be allowed to be discharged back to the stream. A State maintained that this was an unwarranted exemption from NPDES requirements. The existing regulation has been interpreted by some as imposing an absolute ban on clarifier

sludge discharges, although on its face it only bans net credits for such discharges. The proposal was interpreted to allow these discharges without restriction, except for restrictions required to meet water quality standards.

After review of all of the comments on this issue, EPA has decided that both extreme positions are undesirable. Discharge requirements for discharges of raw water clarifier sludge and filter backwash are best determined at the local permitting level after consideration of the appropriate technology-based effluent limits and water quality standards. Since there are no national guidelines for these discharges, they must be limited on a case-by-case basis according to the permit writer's Best Professional Judgment (BPJ), with more stringent limits if necessary to meet water quality standards. The particular technology used to determine BPJ technology-based effluent limits depends on the application of the statutory criteria for different levels of control, for example, best practicable or best conventional technology. These regulations are intended neither to ban such discharges nor to prohibit permit authorities from imposing such a ban in specific cases where this is the appropriate standard for control.

An environmental group commented that the proposed tests for similarity of generic pollutants may not be adequate to fulfill the objectives of the Clean Water Act, especially with regard to water quality. Their concern was that generic pollutants in the influent which were composed of relatively non-toxic constituents would be credited against more harmful constituents in the effluent. On the other hand, an industrial commenter said that the proposed tests to show substantial similarity of generic pollutant parameters are much more reasonable than the existing rule. In general, EPA believes that the "substantial similarity" approach (as opposed to demonstration of identical chemical, physical and biological characteristics) appropriately provides greater flexibility to permit writers in considering requests for net credits, but nevertheless provides adequate protection against environmental harm. However, EPA agrees that strict application of only one of the three tests for demonstrating substantial similarity suggested in the proposal, in some cases, may not provide adequate protection. Therefore, the three tests of the proposal have been replaced in today's final regulation with a more flexible regulation which relies more heavily on the exercise of judgment by the permit writer. The tests specified in the proposal may still be considered by permit writers. However, other alternatives may be required where necessary for adequate protection.

An industrial commenter asked for more flexible specification of the definition of "control system" arguing that net credits should be available in cases where the control strategy intended to be employed to meet permits limits involves management practices, such as a chlorine minimization program, rather than physical treatment technology. As explained in the preamble to the proposal, control system means any control measures considered by permit writers in developing effluent limitations which are applied by the permittee to wastestreams in order to meet the technology-based limitations and standards established in the permit. This includes measures such as chlorine minimization programs. This regulation is not intended to require the installation of specific treatment technology in all cases (e.g., in many cases it may not be necessary, or even useful, to run noncontact cooling water or raw water clarifier sludge through the same treatment system designed for process waters). Nor would this regulation bar a permitting authority from requiring treatment technology, other controls, or zero discharge in a particular case. In considering net credit requests permit writers should examine the control measures that were intended to be employed to meet the applicable permit limits.

Another industrial commenter wanted net credits to be available for water quality-based standards. A State also raised water quality concerns. The proposed regulation included a section stating that the regulation did not preclude consideration of intake pollutants in setting water quality based limits. For the following reasons, EPA is deleting this section as unnecessary. This regulation deals only with technology-based standards. The Clean Water Act's requirement to protect and enhance water quality is not conditioned on factors such as intake water quality and it would be inappropriate for EPA to impose such a condition. Eligibility for a net credit under these regulations does not imply any right to violate water quality standards. However, EPA recognizes that implementation of water quality-based standards is a complex balancing and consideration of many facilities and many factors and that, in setting water quality based permit limitations, a permit writer may take into account the presence of intake water pollutants, as appropriate. Of course, in any case limits must be adequate to meet the water quality objectives of the Clean Water Act when considered along with control requirements for other dischargers to the stream.

An environmental group maintained that the provision that dischargers need not incur significant additional expense to remove intake pollutants amounts to an economic variance which is illegal under the Clean Water Act. EPA does not agree with this contention. EPA is not authorizing variances from the applicable effluent limitations based on the costs to a particular permittee to meet these. Rather, EPA is recognizing that in meeting these limitations the permittee should not be responsible for additional incidental removal of intake pollutants where this would result in significant additional costs. EPA believes this comports with the Fourth Circuit ruling in *Appalachian Power*. In addition, we note that net credits are only available to the extent needed to meet applicable limitations.

*4. EPA action.* The issue of net/gross credit presents difficult problems. While in certain circumstances credits may be appropriate, there are abundant possibilities for abuse. Attempts by EPA to deal with this situation in complicated and detailed regulations do not seem to have resolved these problems and may have unduly restricted the legitimate use of net credits. Therefore, EPA has decided to restructure the regulation, preserving the best of the existing rule and settlement proposal, but simplifying it and providing for more discretion by the local permitting authority. This should make the granting of net/gross credits on a reasoned basis more workable and less arbitrary.

Three particular situations merit specific comment. First, "proper" operation of the control system as required in § 122.45(g)(1)(ii) could arguably be interpreted to require the permittee to incur significant additional expense (such as additional chemical cost) to treat as much of the pollutant present in the effluent as the system is capable of removing. EPA intends that if the permittee would incur significant additional expense above those contemplated in the development of effluent limitations in achieving the incidental removal of intake pollutants the discharger should qualify for a credit to account for these. EPA cannot place a precise figure on what is a "significant" additional cost. This determination must be made on the basis of site-specific

information during the individual permit process. Similarly, when a company is adding a pollutant (e.g., chlorine) only during certain times, it need not continuously operate the system intended to remove that pollutant, but rather only needs to operate as necessary to remove the pollutant added, if it would require significant additional expense to add more chemicals to also control the pollutants present in the intake water.

Second, raw water clarifier sludges and filter backwash, if discharged, are subject to NPDES regulations as are any other discharges of pollutants. Consideration must be given to any additions to the intake water by the permittee, such as the use of flocculants. Since, as described above, EPA believes that these discharges are best dealt with outside the context of net/gross, the language in the proposal concerning raw water clarifier sludges has been deleted. Further, to avoid the improper use of the net/gross regulation to avoid appropriate technology-based limitations on these discharges, a provision has been added to remove them from coverage under net/gross.

Third, a large volume of non-process water, such as non-contract cooling water, is frequently combined with a relatively small volume of process water. An otherwise appropriate grant of net credits for the non-process water could conceivably lead to outfall limits so high as to mask inadequate process water treatment. If a net credit is deemed appropriate in such a situation, the permit writer should set additional limits, under § 122.45(g)(2), to assure proper removal of process water pollutants. These limits may cover the generic pollutants immediately after the process water treatment system or more specific process water pollutants at the outfall. Finally, ineligibility of a facility for net/gross credits under this regulation does not affect that facility's right to apply for a fundamentally different factor (FDF) variance.

**H. Total Metals (40 CFR 122.45(c) [CPR § 122.63(c)])**

1. *Background.* Metals in water occur in both dissolved and solid forms. There are three methods for measuring the level of metals in water. Each of these methods will give a different result depending upon the amounts of metals which are in each form. The total metals method uses a strong acid digestion to dissolve solids and measures both dissolved and solid metals. The dissolved metals method uses filtration to remove solids and measures only dissolved metals. The total recoverable metals method is an intermediate method which uses a weak acid treatment to dissolve readily soluble solids and filtration to remove residual solids. Details of these methods may be found in the publication "Methods for the Chemical Analysis of Water and Wastewater", EPA–600/4–79–020, March, 1979.

Decisions on how to measure metals in effluents must be made when establishing permit limitations and compliance monitoring requirements. These decisions are complicated by the chemical and biological processes that occur when effluents combine with receiving waters. Additionally, what ultimately happens to these pollutants in the receiving waters is very complex. Metals in solid form may dissolve and, although somewhat less likely, metals in dissolved form may change to solid. (See "Water Related Environmental Fate of 129 Priority Pollutants", EPA–440/4–79–029a.)

2. *Existing rules.* The current regulation takes the conservative approach of regulating metals as total metals, unless otherwise specified in a nationally promulgated effluent limitations guideline (guideline) or the permit writer in setting case-by-case permit limitations determines that a different method of measurement is appropriate. This approach is based on the assumption that all solid metals have the potential to dissolve and adversely affect the environment.

3. *Proposed changes.* Industry litigants claimed that only dissolved metals were environmentally significant and, therefore, that the appropriate method of measurement should be dissolved metals. EPA disagreed with this claim because of the complex chemical and biological processes that occur when effluents combine with receiving waters. For example, metals in the effluent of an electroplating facility that adds lime and uses clarifiers will be a combination of solids not removed by the clarifiers and residual dissolved metals. When the effluent from the clarifiers, usually with a high pH level, mixes with receiving water with a significantly lower pH level, these solids instantly dissolve. Measuring dissolved metals in the effluent, in this case, would underestimate the impact on the receiving water. Measuring with the total metals method required by the existing regulations, on the other hand, would assure no violation of water quality. Furthermore, proper sizing and operation of the clarifiers is a necessary part of the technology of reducing metals to acceptable levels. Measuring dissolved metals in the effluent would mask any inadequacies in the clarification step.

EPA, therefore, proposed a lesser relaxation of the existing rule, using total recoverable metals as the general standard, unless otherwise specified in a guideline or the permit writer determines other measures are appropriate. This standard for determining the level of metals in the effluent would measure dissolved metals plus that portion of solid metals which can easily dissolve. This is intended to measure metals which are or may easily become environmentally active, while not measuring those which may be expected to settle out and remain inert.

4. *Comments and responses.* An industrial commenter wanted the use of the total recoverable metals method extended to cases where guidelines are based on total metals. However, as stated in the preamble to the proposal, data using total metals and that using total recoverable metals are not interchangeable. Therefore, EPA could only change the guidelines measurement method based on compilation of a new data base. This would be a large and extensive undertaking and would adversely affect EPA's ability to address important priorities. Such a disruption to program implementation is unwarranted and would conflict with court ordered deadlines. Where guidelines specify total (or dissolved) metals, that is the method to be used.

Several commenters stated that data based on total recoverable metals are not readily available. This is generally true at this time. Where effluent data based on total metals are being used to set permit limits (such as treatability manual data used for a "best professional judgment" determination), the permit writer may need to gather additional comparison effluent data using both methods. Data involving water quality standards is quite a different case. Analytical methods used to set water quality standards are not uniform and often vary within, as well as among, States. Consequently, when using data based on water quality standards to set effluent limitations, permit writers may discover that these data were derived from any of the three methods of measuring metals in the receiving water. However, because of the complex processes that occur when effluents combine with receiving waters, it is not possible to relate directly the form of the metals in the effluent to those in the receiving water. Therefore, it is not necessary to use the same analytical method used in developing the water quality standards for

developing effluent limitations. EPA's intent in promulgating this regulation is to endorse the total recoverable method as the best predictor of effluent impact on water quality. Using the total recoverable method to set water quality-based effluent limitations is independent of the method used to develop water quality standards for the receiving water.

Several commenters asserted that this standard is not sufficiently environmentally protective since metals excluded from total recoverable metals (but included in total metals) could eventually dissolve and affect water quality. A particular concern was an accumulation of slowly dissolving solid metals on the bottom of a water body. There are little or no data available on such long term environmental effects. To some extent these slowly dissolving solids will either disperse or be covered over, lessening any potential impacts. EPA has concluded that the total recoverable metals method is the most reasonable approach because it gives results that best approximate the amount of metals that are likely to produce water quality impacts. While all the metal measured by the total metals method could eventually disslove, the portion of total metals represented by total recoverable metals is a better measure of potential adverse environmental impact.

An industry commenter asked that the phrase "dissolved or valent or total" in § 122.45(c)(1) [CPR § 122.63(c)(1)] and 122.45(c)(2) be revised to "dissolved or ionic or valent or total" and that the word "dissolved" in § 122.45(c)(3) be expanded to "dissolved or ionic." The commenter wished to make these sections include specific simple or complex metal ions. (A complex metal ion is a combination of a metal with other chemical compounds.) EPA agrees in part with this comment. The term "valent" in § 122.45(c) (1) and (2) is intended to include simple or complex metal ions. Section 122.45(c)(3) is also applicable to simple or complex metal ions. However, the commenter wished to use the sections to encourage the regulation of specific simple or complex ions. EPA disagrees that the regulation of metals as specific simple or complex ions is useful or desirable. The general standard to be applied is *total* recoverable metal, since metals may change form in receiving waters or elsewhere in the environment. Also, the NRDC consent decree [8 ERC 2120 (D.D.C. 1976)] requires EPA to regulate all compounds containing the specified toxic metals. While some complex ions have strong bonds, many are weak and easily convert to other forms, especially when passing from an effluent to the receiving water. Therefore, it is important to control all ions containing the metal. Also, practical difficulties would arise since the analytical methods for distinguishing specific simple or complex metal ions are often complicated, sensitive, and prone to error. The single known example of a case where it may be useful to regulate a specific ionic form is hexavalent chromium. The strongly oxidized state of this highly toxic ion makes its formation from other chromium in the environment essentially impossible. Furthermore, hexavalent chromium limits are frequently used in addition to total chromium limits, rather than as a substitute for total chromium.

*5. EPA action.* EPA is today promulgating, unchanged, the proposed regulation. By choosing a total recoverable metals standard, the use of dissolved metals limits is being strongly discouraged, especially for toxic metals. Except where otherwise provided in guidelines, or where required in highly unusual cases to implement the Clean Water Act, metals limits in permits should be stated as total recoverable metals.

**I. Actual Production § 122.45(b)(2) [CPR § 122.63(b)(2)]**

*1. Existing rule.* The existing regulation requires production-based permit limits to be based upon a reasonable measure of actual production, not upon the design capacity of the facility. This requirement is intended to assure that facilities operating below full capacity are treating their wastewater to the extent required by the Clean Water Act's technology-based treatment requirements, rather than enjoying relaxed limits due to unused production capacity. Such an approach also assures equity among facilities in the same industry, regardless of their design capacity.

*2. Proposed changes.* Industry litigants expressed concern that, especially for cyclical industries which are currently in a slump, estimates of projected production should be allowed where the historical measures of actual production may not be reasonable predictors of future production. They also were concerned that should production increase beyond the level on which the permit was based, the permit modification process might not be fast enough to respond to the need for a higher production based limit in the permit. The proposal, recognizing the unique nature of the auto industry, in which demand is extremely volatile and the Director may not be able to modify permits to increase effluent limitations with sufficient speed to allow increased production, provides for alternate effluent limitations for that industry. The proposal requires EPA, and allows States, to write alternate permit limits for the automotive manufacturing industry if the applicant satisfactorily demonstrates that its actual production is substantially below maximum production capability and there is a reasonable potential for an increase above actual production during the permit term. Under the proposal, a permit could be written providing more than one permit limitation—one based on the discharger's current production level and one or more based on potential increased production rates. For example, a hypothetical automotive plant with historic production of 60% of capacity might have a permit limit on pollutant "X" of 2 pounds per day. The alternate limits might be 2.5 pounds per day for production from 61–80% of capacity, and 3 pounds per day for 81–100% of capacity. If the plant's production for a month was in the higher range, then it could discharge up to the corresponding higher effluent limitation. The proposal also required monthly notice of anticipated production increases.

In addition, the preamble to the proposal clarified that the operative requirement is that the permit be based on a reasonable measure of actual production and the examples cited in the regulation are not meant to be all-inclusive, but are merely illustrative.

3. *Comments and responses.* Many commenters supported the concept of alternate permit limitations as allowing companies to respond quickly to changes in the market. Several commenters suggested that the concept also be applied to other industries besides the auto industry. EPA agrees that alternate permit limits may be useful in developing permits for other industrial categories and therefore has revised the final regulation to explicitly provide that EPA and the States have the discretion to adopt such limitations. Use of alternate limits is mandatory only where EPA writes permits for discharges associated with the automotive manufacturing industry if the discharger makes the requisite demonstration. Only the automotive industry has clearly demonstrated the need for the alternative limits. In all other situations, alternate limits will be used at the discretion of the permit writer, although dischargers may request the use of such limits. For approved NPDES States, the use of

alternate permit limitations is discretionary even for the automotive manufacturing industry.

It should also be noted that alternate permit limitations may also be appropriate where a decrease in production is expected to occur during the term of the permit, such as in industries where the production reported on the application is significantly higher than the long term production. Today's rulemaking clarifies that, on a case-by-case basis, the permit writer may provide for alternate limits based upon possible declining production.

EPA anticipates that alternate permit limitations will be used in instances where historical production levels are not indicative of expected future production. The alternate limits approach, however, is not a substitute for the permit modification process or a cure-all for other problems, such as bypass situations, which are addressed separately in the regulations. Alternate permit limitations are appropriate only when production is expected to change so substantially during the permit term that a single set of permit limitations could not adequately cover all the production levels. Permit writers, however, are not required to consider all possible contingencies or to address all anticipated fluctuations in production rates with alternate limits.

As pointed out by one commenter, although providing increased flexibility, the regulatory change will require increased technical supervision to ensure that permit conditions are not violated. Therefore, when they are used, the alternate permit limitations generally should be based upon a tiered approach, providing, for example, 2 or 3 alternative limits based upon reliably anticipated ranges of production levels. Because of the administrative and enforcement difficulties, the permit should generally not entail the use of a continuum of effluent limitations based upon all possible production levels up to capacity. However, permit writers have the flexibility to include a continuum where appropriate, such as for industries likely to have daily production fluctuations that cannot adequately be accounted for otherwise.

Another commenter suggested that the permit contain limits on both pounds per day of pollutant per unit production (essentially a continuum), and pounds per day based on production capacity or recent historic or projected production, in order to avoid the requirement to report at the beginning of each month when production is expected to rise to higher alternate levels. We have not chosen this approach since, as discussed above, it is more difficult to effectively regulate and monitor compliance of dischargers using permit limits based upon a continuum. Should a permit writer, however, on a case-by-case basis find such an approach useful, the regulations provide sufficient latitude. In addition, as discussed below, the final regulation has addressed the reporting requirements concern and reduced the reporting burden to a minimum. Furthermore, notification of increased production levels is not required when the permit includes a continuum, rather than a tiered approach.

Several other commenters thought that the reporting requirements should be changed. One commenter thought that it may not always be possible to give advance notice two business days before each month of production increases. Although a discharger may not always be certain that production will change two business days before the ensuing month, he nevertheless will know whether there is a reasonable likelihood. It is a good business practice to conduct advance planning of production levels on at least a monthly basis so that production personnel, materials and other factors can be coordinated. Since the notification process is only two days in advance of monthly production change, information concerning the likelihood of a change should be readily available to the permittee. If the permittee thinks there is a reasonable likelihood that production will increase, he should submit a notice indicating the anticipated production level, otherwise he would not be eligible for the higher limit. The notification requirement may also benefit permittee pollution control programs since it will encourage permittees to effectively plan and coordinate their pollution control programs and production levels.

Of course, when the discharger submits notification, the higher limit applies only if the production actually increases. If production does not increase, the permittee must comply with the limitations applicable to the actual production for the period. Thus, permittees are not rewarded for overestimating future production. EPA and States will track compliance against limitations corresponding to actual production, irrespective of any notices submitted by permittees. To track compliance in any other way would be unfair to permittees or would benefit dischargers that inflate production values.

The notification requirement applies whenever a permittee wants to be eligible for a discharge limit other than the lowest limit in the permit. The notice, however, does not have to be limited to an ensuing 30 day period, as EPA proposed, if the discharger expects to qualify for a higher limitation over a longer period of time. For example, if a discharger expects to be producing at a higher level for six months, the Agency sees no reason for requiring notification before each month. When submitting the notice of future discharge levels, the permittee should specify the period of time for which the higher anticipated level will apply. If the period covered by the notice extends beyond the ensuing month, then the notice should specify the reasons why the higher production level is anticipated. A new notice is required (1) to cover a period or production level not covered by a prior notice or (2) if during two consecutive months otherwise covered by a notice, the production level at the permitted facility does not in fact meet the higher level designated in the notice. Permitting authorities will assume that the facility is operating at the higher level (except for possibly an interim month) until the end of the noticed period or until a new notice is received indicating production at an even higher level (although compliance will still be tracked against the actual production levels).

The notices will provide inspectors with the knowledge of the levels at which the facility expects to operate at the time inspections are performed. The discharge monitoring report (DMR) for each period must contain the level of production that actually occurred. Dischargers must also identify on the DMR the permit limits that correspond to the actual production level, since EPA will track compliance against such limits.

Furthermore, to obtain the actual production figures and determine applicable limits for compliance monitoring purposes as soon as possible, it will usually be appropriate for dischargers with alternate permit limits to submit DMRs on at least a monthly basis. EPA does not expect monthly submission to result in a change in total reporting burdens, since the dischargers most likely to have alternate limits are generally major facilities with monthly DMRs requirements in their current permits.

One commenter objected to the reporting and publicizing of anticipated production schedules and actual production figures. Anticipated production information is vital to the permit writer if the Agency is to provide alternate permit limits. Actual production figures also must be reported to EPA in order for EPA to determine compliance with the appropriate

discharge limit. Although this information would be available to the public upon request, EPA does not plan to publish the information. However, to restrict access to this information would prevent the public from evaluating compliance.

A few commenters pointed out that the preamble to the proposed regulations was helpful in clarifying the "reasonable measure of actual production" standard. As stated in the preamble to the proposed regulation, § 122.45(b)(2) [CPR § 122.63(b)(2)] requires that production based permit effluent limitations be based on some "reasonable measure of actual production of the facility, such as the production during the high month of the previous year, or the monthly average for the highest of the previous 5 years." As stated in the preamble to the proposal, the operative requirement of this provision is that the permit be based on a reasonable measure of actual production. The examples given are simply examples, and merely illustrate typical acceptable measures. Other measures of actual production are entirely acceptable if the Director finds them "reasonable". To clarify that the examples are not the operative requirement, EPA has deleted them from the final rule. The regulations will now only require use of a reasonable measure of actual production.

In addition, the alternate permit limitations approach should avoid the controversial nature of determining actual production. Instead of having permit limitations potentially based upon a "worst case scenario", i.e., the period of maximum production, alternate limitations allow the limitations to correspond to varying production levels. Thus, when alternate limits are used, average production measures can be used as one reasonable measure of actual production, unless an effluent limitations guideline specifies otherwise. For example, the alternate permit limitations approach would allow permit writers to take into account changes in production levels using long-term average values, instead of relying on a short-term maximum level of production to cover normal day-to-day variations.

One commenter provided specific descriptions of two facilities which he thought met the criteria of the examples of a "reasonable" measure provided in the preamble. It is not appropriate to respond to specific permit situations in the context of these general regulations since all the facts of the situation may not be available.

One commenter objected generally to the use of mass-based (as opposed to concentration-based) limits and particularly those based on production. Permit writers are encouraged to express limits in terms of both mass and concentration. Mass-based limits are necessary and encouraged to prevent the use of dilution as a means of treatment and also, where water quality is limiting, control total loadings in regard to the assimilative capacity of the receiving water body. Concentration-based limits ensure proper operation of treatment facilities regardless of raw wastewater load and protect against water quality impacts where pollutant concentration is important (e.g. toxic pollutants). The amended regulation provides the procedural means for implementing production-based limits. Comments about the appropriateness of a production-based limit should be submitted during the comment period for the relevant effluent guideline or where the limit is not based on a guideline, for the draft permit.

*4. EPA action.* EPA has expanded the proposal. The final regulation allows industries other than automotive manufacturing to be covered by alternate permit limitations and alternate limits to be written if there is an expected increase or decrease in production levels during the permit term.

**J. Imposition of Water Quality Conditions Stayed by a Court or Agency (40 CFR 122.44(d)(3) [CPR § 122.62(d)(3)])**

*1. Existing rules.* Section 401 of the CWA requires EPA, before issuing an NPDES permit, to obtain from the State in which the discharge originates a certification that the discharge, under the terms of the permit, will comply with State legal requirements, including water quality standards. If the State waives certification or fails to act within a "reasonable period of time (which shall not exceed one year)," then EPA may issue the permit without certification.

Section 124.53 of the NPDES regulations provides that the State will be deemed to have waived certification of the conditions in a draft permit if it has not responded within a specified time, not to exceed sixty days, unless the EPA Regional Administrator authorizes a longer period. This waiver period assures that the issuance of NPDES permits is not delayed until State certification issues are resolved in all cases. Generally, sixty days have proven to be a reasonable and achievable time frame for certification.

In addition, § 122.44(d)(3) [CPR § 122.62(d)(3)] provides that if a State certification is stayed by a court or State board or agency, EPA shall include conditions in the permit which may be necessary to comply with section 301(b)(1)(C) of the Clean Water Act. Section 301(b)(1)(C) requires NPDES permits to include any more stringent limitations established under State law or regulations or any other Federal law, including those necessary to meet water quality standards.

*2. Proposed changes.* EPA proposed that, if a State certification is stayed by a court or by a State board or agency, States would have sixty days in which to submit the certification before the certification is deemed waived. The proposal responded to the industry litigants' concern that if EPA issues the permit without giving the State an opportunity to resolve its proceedings, the State's proceedings would effectively be moot. The proposed regulation would allow a State an opportunity to complete its review proceedings prior to the issuance of the permit.

*3. Comments and responses.* Some commenters recognized the proposed rules as a reasonable compromise between EPA's interest in prompt permit issuance and the permittee's interest in ensuring that his permit incorporates finally effective State requirements which may have been revised as a result of their being challenged. Other commenters questioned EPA's authority to deem certification waived within sixty days as being inconsistent with section 401(a)(1) of the Act. They suggested a longer period of time (e.g., from six months to a year) is warranted, since it is unlikely that a State could complete judicial or administrative proceedings in sixty days.

According to the legislative history of this provision, the State certification procedure was included in the CWA to provided a State water pollution control agency an opportunity to determine whether or not effluent limitations established for dischargers in an EPA issued permit are at least as stringent as any applicable State requirements. (See Senate Consideration of the Report of the Conference Committee, October 4, 1972, 93rd Cong., 2d Sess. (1972), reprinted in Environmental Policy Decision of the Library of Congress, A Legislative History of the Water Pollution Control Act Amendments of 1972, 93rd Cong., 1st Sess., 176, Serial No. 93–1, hereinafter referred to as Legislative History.) Section 401(a)(1) requires the Agency to provide a reasonable period of time, not to exceed one year, before State certification is deemed waived. The waiver provision of section 401 was provided to assure that a State's inaction would not

frustrate the application for a federal permit. See H.R. Rep. No. 92-911, 920 Cong., 2d Sess., 22 (1972) reprinted in Legislative History, p. 809.

In choosing a "reasonable time period", the Agency had to balance the opportunity for a State agency to evaluate and assure compliance with State requirements, the permittee's interest in assuring that its permit reflects State regulations which may ultimately be revised as a result of their being challenged, and the goals of the Clean Water Act to assure prompt permit issuance and compliance with statutory deadlines. In § 124.53 EPA chose sixty days as the waiver period, agreeing with commenters that delays caused by the State certification process to the NPDES program would be unwarranted if a year were allowed for certification, See 44 FR 32880 (Revision of NPDES regulations, June 7, 1979). Consistent with that determination, today's rulemaking would provide another sixty day period prior to issuance of the permit if the certification is stayed by a court or State board or agency.

EPA recognizes that in some instances States will not be able to resolve their proceedings in sixty days or even in one year, the maximum time allowed under section 401(a)(1) of the CWA. In some cases, however, States can complete review proceedings quickly. EPA has concluded that it is reasonable to allow sixty days from the staying of a certification for a State to resolve issues. This time frame is consistent with the original certification period provided in § 124.53 and is based on the same balancing of interests reflected therein.

It is important that NPDES permits be issued in a timely fashion to assure compliance with the Act and, where necessary, to avoid unwarranted delays in the construction and operation of new facilities. No evidence has been submitted to EPA demonstrating that a six-month time period, or any other alternative period, would assure resolution of a significantly larger number of State proceedings so as to warrant delays in the NPDES permit issuance process.

Sixty days is a minimum time period and does not preclude EPA from delaying permit issuance if it is apparent the State decision is imminent. On a case-by-case basis, EPA has the discretion to wait and incorporate the State decision. In addition, even if EPA chooses to proceed, if a modified State certification is received prior to final Agency action on the permit, the permit will be modified to issuance, if necessary, to be consistent with the certification. See § 124.55.

Regardless of whether a State has certified or waived certification, EPA has an independent obligation to include in permits limitations necessary to comply with State law. See section 301(b)(1)(c) of the CWA and Decision of the General Counsel No. 58 (March 29, 1977). Any permit issued by EPA must protect the State's interest by assuring compliance with State standards. In addition, the permittee's interests are protected even after EPA has issued the permit. If the State proceedings determined that a State standard which has been incorporated into the permit is invalid, the permittee may seek a permit modification.

One commenter stated that the proposal provides a discharger opposed to conditions of State certification with the incentive to intentionally delay State proceedings. The commenter suggested that the certification should not be deemed waived if the State is unable to complete judicial or administrative proceedings due to the discharger's failure to cooperate.

EPA disagrees that its proposal provides an unfair incentive for intentional delays. EPA's ability to proceed with permit issuance after 60 days, regardless of whether State proceedings have been completed, in most cases will eliminate any advantage to delay. In situations where a discharger is delaying solely because it believes a determination by EPA will be more advantageous, EPA does have the ability to extend the 60 day period to allow more time to complete State proceedings. In addition, the new regulation in fact makes it more difficult for a discharger to avoid the State certification requirements because it provides the State with an additional sixty days in which to complete State proceeedings beyond that provided in the current regulations. However, we caution that EPA should not become involved in findings of fact as to whether lack of resolution of a State's proceedings is due to a discharger's failure to cooperate.

One commenter suggested that alternative means, such as the State/EPA agreement, be used to deal with permit certification "log jams" that may occur. EPA recognizes that the State/EPA agreement and other means may be needed to assure timely State certification and this is not precluded by the regulations. It is always preferable, from EPA's standpoint as well as the States, to have State certification prior to EPA's issuance of a permit and EPA will continue to work to assure that this is done. The regulations, however, are needed to assure a consistent method of dealing with the unusual case of procedural delay.

*4. EPA action.* Based on review of the proposal and the comments, the amendment is promulgated as proposed.

**K. Incorporation of NEPA-based Conditions in Permits (40 CFR 122.7(g) [CPR 122.12(g)], 122.29(c)(3) [CPR 122.66(c)(3)], 122.44(d)(9) [CPR 122.62(c)(9)], 124.85(e), 124.121(f))**

*1. Existing rules.* Under section 511(c) of the CWA, the issuance of an NPDES permit to a new source is subject to review under the National Environmental Policy Act of 1969 (NEPA). This may require the preparation of an Environmental Impact Statement (EIS). Several sections of the NPDES regulations deal with the incorporation of EIS-related conditions in new source NPDES permits. Section 122.44(d)(9) [CPR § 122.62(d)(9)] provides that when EPA is the permitting authority, new source permits shall incorporate requirements, conditions or limitations under NEPA and section 511 of the CWA. Similarly, § 122.29(c)(3) [CPR § 122.66(c)(3)] requires Regional Administrators to issue, condition, or deny new source permits after a NEPA review, including an EIS, if prepared. Section 122.47(g) [CPR § 122.12(g)] notes that NEPA may require the inclusion of EIS-related conditions, as described in § 122.29(c)(3).

*2. Proposed changes.* In response to litigants' concerns that NEPA could not legally be used as broadly in the permit process as EPA regulations provided, EPA proposed several changes. First, EPA proposed to modify §§ 122.7(g), 122.29(c)(3), and 122.44(d)(9) to clarify that NEPA cannot be used to review effluent limitations or other requirements established by the CWA or to set such effluent limitations. Section 511(c)(2) of the CWA expressly prohibits the use of NEPA for such purposes. EPA also proposed to revise these sections to explain that, in all other respects, the regulations take no position on the circumstances under which NEPA conditions (other than effluent limitations) may be imposed in NPDES permits. The proposal was intended to eliminate the implication that EIS-related conditions must be incorporated in permits and to allow the appropriateness of EIS-related conditions (including whether any such conditions should be incorporated) to be resolved in the context of specific permit issuance.

EPA also proposed a new section to its evidentiary hearing rules (§ 124.85(e)) to provide that evidence of

environmental impacts of a facility may be submitted at an evidentiary hearing concerning a new source subject to NEPA if the evidence would be relevant to the Agency's obligations under § 122.29(c)(3). This proposal would also apply to Non-Adversary Panel Procedure (NAPP) hearings through a revision to § 124.121(f). (The existing evidentiary and NAPP hearing regulations contain no specific provisions concerning the admission of evidence on environmental impacts.) In addition, for sources that hold final RCRA, PSD, UIC, or ocean dumping permits, the proposal would also bar the admission of evidence and cross-examination related to environmental issues that were or could have been considered in the permitting proceedings for these permits. Under the proposal, the Presiding Officer would have the discretion to admit portions of the record from those permit proceedings in order to fulfill evaluation obligations. The proposal was intended to avoid having an evidentiary or NAPP hearing on an NPDES permit subject to NEPA become a forum for reexamination of decisions under other statutes to which NEPA does not apply. The proposed rule would thus limit the scope of evidence that could be submitted at hearings to the scope of analysis required under NEPA.

*3. Comments and responses.* One commenter supporting the proposal states that EPA has no authority to include EIS-related conditions in permits. Several others added that EPA could only impose NEPA conditions related to the permitted discharge. An opposing commenter objected that the proposed change violates NEPA and reverses EPA's previous interpretations that EPA could condition or deny a permit based upon non-water quality impacts.

After careful consideration of these comments and the statutes, the Administrator has determined that NEPA, in conjunction with the CWA, authorizes the Agency to deny or impose conditions, including non-water quality related conditions, in NPDES permits on the basis of the NEPA review. Section 511(c)(1) makes clear Congress' intent that NEPA applies to the issuance of an NPDES permit to a new source. That review might be meaningless if EPA had no authority to consider and act upon its results. Thus, EPA has consistently taken the position that EPA can take appropriate actions by conditioning or denying the permit to mitigate or prevent unacceptable environmental impacts identified by the EIS. This position is supported by the legislative history of the CWA and NEPA case law. (See Opinions of the General Counsel Nos. 76–18 and 76–19 (September 23, 1976).)

The authority to include conditions related to the EIS would also apply to non-water quality impacts identified in the EIS. Section 511(c) does not limit the scope of the NEPA review, except to prohibit EPA from reviewing or establishing effluent limitations. EPA interprets this to imply that the Agency may consider all other results of the environmental review. The Administrator may impose appropriate non-water quality conditions using his authority to condition or deny permits under section 402(a)(1) of the CWA.

The proposed regulation would not change this position. NEPA does not mandate that EPA take any particular action as a result of a NEPA review, but rather grants the Agency discretion to determine what action is appropriate. EPA's change to the provisions related to NEPA conditions will still authorize EPA to impose such conditions. The only changes will be (1) to allow questions of whether particular permit conditions based upon the EIS are appropriate or authorized to be resolved in the permit issuance process and (2) to remove any implication that EPA must always include such conditions.

A commenter asserted that NEPA requires that EPA consider using more stringent effluent limitations to satisfy NEPA requirements. It was suggested that "there may be circumstances in which, for an individual site, more stringent effluent limitations ought to be considered since they may provide a better balance of costs and benefits than would non-water quality conditions that EPA could impose in the permit. Since this suggestion directly conflicts with the language of section 511(c)(2), EPA concludes that it would not be permissible under the statute. EPA may consider the entire EIS in deciding whether to issue or deny an NPDES permit or include mitigating measures other than effluent limitations, but EPA has no authority to establish or review effluent limitations based upon the NEPA review. More stringent limitations may not be imposed if not otherwise authorized by the CWA. EPA does have authority to impose limitations in addition to those in an applicable New Source Performance Standard (NSPS), under section 402(a)(1) using the permit writer's best professional judgement (BPJ), if an NSPS does not address a particular waste stream or pollutant present in the discharge and it is determined such controls are necessary. (See discussion above, Part F.) In such a case, NEPA would not be the basis for establishing such BPJ limitations, but rather EPA would develop such limitations as necessary to meet the requirements of the CWA, using information from the EIS in addition to other sources. EPA can also impose limits more stringent than an NSPS where necessary to comply with water quality standards or address other water quality concerns, even if the EIS was used to identify the impacts.

Another commenter stated that the proposal conflicted with the New Source Performance Standards for the Ore Mining and Dressing Point Source Category (40 CFR Part 440; 47 FR 54598, December 3, 1982). That standard specifically exempted the Quartz Hill Molybdenum Project from coverage under the standard (§ 440.100(b)) to allow full consideration of non-water quality environmental impacts through an EIS the NEPA review was triggered by the Alaska National Interest Lands Conservation Act, not the CWA). (See 47 FR 54601, December 3, 1982). The commenter stated that the proposed change would eliminate all possible bases for the development of an NPDES permit.

EPA does not agree that the revision will make permit issuance impossible. The Quartz Hill Project is not a new source within the definition of § 122.2 [CPR § 122.3], since it is specifically excluded from the Ore Mining NSPS and is not covered by another NSPS. Therefore, the NPDES permit for the facility will be based on the permit writer's BPJ under section 402(a)(1) of the CWA and the Director may include such conditions as are necessary to comply with the Act. In issuing the permit, the Director may use all available information to determine what effluent limitations are necessary to meet the requirements of the CWA. This information could include the EIS.

Several commenters opposed EPA's proposed limitations on the admission of evidence at evidentiary and NAPP hearings. One of these suggested that issues that were not raised in the prior permit decision should not be barred in the NPDES permit hearings. Another suggested that the Presiding Officer should be authorized to make an independent determination of whether to allow admission of evidence. EPA has concluded that these suggestions could allow undue complication of NPDES proceedings. The proposal eliminates unnecessary duplication of effort and relitigation of issues while still ensuring that EPA meets its NEPA review responsibilities. EPA does not interpret the limited applicability of NEPA to new

source NPDES permit proceedings under section 511(c) to authorize reexamination of determinations made by EPA under other statutes to which NEPA does not apply. For example, PSD determinations, like all EPA determinations under the Clean Air Act, are exempted by statute from NEPA's EIS requirements. (See section 7(c)(1) of the Energy Supply and Environmental Coordination Act, 15 U.S.C. 793(c)(1).) The limitation on the admission of evidence also carries out Congress' directive in Section 101(f) of the CWA that "the procedures utilized for implementing this Act shall encourage the drastic minimization of paperwork and interagency decision procedures, and the best use of available manpower and funds, so as to prevent needless duplication and unnecessary delays at all levels of government."

In response to the comments, EPA has modified the final rule to clarify that the limitations on the admission of evidence at EPA hearings applies only where the previous permit proceedings were held by EPA. EPA cannot delegate its NEPA responsibilities to States. *Stuebing* v. *Brinegar* 511 F.2d (2nd Cir. 1975); *Greene County Planning Board* v. *FPC* 455 F.2d 412 (2nd Cir. 1972), *cert. den.* 409 U.S.C. 849 (1972). Therefore, EPA can limit admission of evidence that could have been submitted at a previous hearing on a permit for the facility under a different program only if the permit was issued by EPA. States approved to administer other permit programs may make decisions on such other permits that address issues relevant to EPA's NEPA review. However, since these issues were previously considered only by the State, evidence on these issues is admissible at an EPA-held hearing for a new source. Otherwise, EPA would have impermissibly authorized the State to carry out EPA's NEPA responsibilities.

*4. EPA action.* The language of today's final rule is the same as the proposal, except for the revision to § 124.85(e) clarifying that the limits on admissibility at hearings of evidence on environmental impacts applies only if the issues could have been raised at prior EPA hearings. Sections 122.47(g), 122.29(c)(3), and 122.44(d)(9) have been revised as proposed to make clear that, under section 511(c)(2) of the CWA, NEPA cannot be used to review effluent limitations or other requirements established under the CWA or to set such limitations. These revised provisions now make clear that, in all other respects, the regulations take no position on particular circumstances under which NEPA conditions (other than effluent limitations) may be imposed in NPDES permits. These revisions do not substantively change EPA's authority to impose EIS-related conditions.

EPA will continue to impose EIS-related conditions in permits in appropriate circumstances. For example, conditions have been used to limit the times of the year during which discharges are authorized where such discharges may have an impact upon fish spawning. EPA has also used EIS-related conditions to require consultation with appropriate State officials by coal mine operators in archeologically important areas. Where a NEPA review indicates that such conditions are appropriate, EPA will use them.

New § 124.85(e) provides that evidence on environmental impacts of a facility may be submitted at a hearing for a new source subject to NEPA if the evidence would be relevant to the Agency's obligations under § 122.29(c)(3). That section, in turn, requires EPA, to the extent allowed by law, to conduct an evaluation of significant environmental impacts of the proposed action. Thus, the scope of the evidence on environmental impacts admissible at a NPDES hearing turns ultimately on the scope of analysis required by NEPA.

In order to minimize delay and duplication of effort, § 123.85(e) also provides that where a source holds a final EPA-issued RCRA, PSD, UIC, or ocean dumping permit, no evidence may be admitted nor will cross-examination be allowed with respect to issues that were considered or could have been considered in those permit proceedings, even as to matters that may have been within the proper scope of NEPA analysis. In such cases, the Presiding Officer may (to the extent required by NEPA) instead admit relevant portions of the record of the PSD, RCRA, UIC, or ocean dumping proceedings. This evidence may be necessary to perform the balancing of costs and benefits required by NEPA.

**L. Compliance Schedule Prohibition (40 CFR 122.47, 122.29(d)(4) [CPR §§ 122.10, 122.66(d)(4)])**

*1. Existing rule.* The current regulations treat new sources, new dischargers and recommencing dischargers differently from existing sources and do not allow them to be placed on compliance schedules to meet permit limitations. Permits issued to existing sources may contain compliance schedules, but new sources, new discharge and recommencing dischargers must install and start up all pollution control equipment prior to discharger and comply with their permit limitations within the shortest feasible time, not to exceed 90 days following commencement. The current regulations treat these dischargers differently because new sources and new dischargers have never operated under a previously issued permit and, like recommencing dischargers which begin to discharge after terminating operations, are considered to be in a better position than existing sources to install and "start up" their equipment and meet their permit limitations. Existing sources, on the other hand, may need additional time to upgrade their treatment technology to meet new permit limitations.

*2. Proposed changes.* Industry litigants challenged the compliance schedule prohibition on the grounds that it was too inflexible and did not address the situation when EPA issued or revised requirements after a facility began to construct but before it began to discharge. Industry argued that such a facility should be given a reasonable time to adjust its equipment to comply with newly issued or revised requirements. In response to these concerns, EPA proposed to allow permits issued to new sources, new dischargers and recommencing dischargers to include compliance schedules which allow those dischargers to meet their permit limitations within a reasonable time after discharge begins rather than in all cases at the time of discharge. Under the proposed regulations, reasonable compliance schedules could be issued to new sources and new dischargers if requirements were issued or revised after construction began but less than three years before they begin to discharge. Because construction is not an issue with recommencing dischargers, the proposal allowed them to be placed on compliance schedules if requirements were issued or revised less than three years before discharge recommences.

*3. Comments and responses.* We received five comments on the proposal. All comments were from industry and all supported the proposed change. One commenter suggested that we should conform the proposed change to the section on new sources and new dischargers.

*4. New action.* Based on the comments received, we are promulgating the final regulation as proposed and cross-referencing it in § 122.29(d)(4) [CPR § 122.66(d)(4)] (New sources and new dischargers).

**M. Notice of Physical Alterations or Additions (40 CFR 122.41(1)(l) [CPR § 122.7(1)(l)]**

*1. Existing rule.* The existing rule requires the permittee to give notice to the Director of any planned physical alteration or addition to the permitted facility. The rule was based on the rationale that notice of such changes would enable the Director to decide whether a permit modification was necessary.

*2. Proposed changes.* The proposed regulation would require permittees to give notice to the Director of physical alterations or additions which could significantly change the discharge. The proposal further provides that this notice applies to pollutants for which the Director would not otherwise receive notice through (1) compliance reporting for pollutants limited in the permit or (2) notification of toxics under § 122.42(a)(1) [CPR § 122.61(a)(1)]. The proposal recognized that many industrial facilities frequently undergo physical alteration or additions which are minor and have little or no impact on a permittee's discharge and thus, reporting all such changes would be unnecessarily burdensome. Notice of only those changes which could result in significant changes to the permitted facility's discharge should provide EPA or the State permitting agency sufficient information to determine the need for permit modification.

*3. Comments and responses.* EPA received ten comments, all supporting the proposal. Several commenters stated that most alterations and additions to industrial facilities are minor and have little impact on the permittee's disharge. Several other commenters felt that the existing rule created an unnecessary reporting burden on permittees. Some commenters noted that the proposal ensured that EPA would receive sufficient information to assess permit compliance and to decide whether permit modifications are necessary.

Commenters also contended that the existing rule exceeded EPA's authority under the CWA. EPA does not agree that the original rule exceeded EPA's authority under the CWA, since EPA has broad authority under section 308 of the Act to require recordkeeping and reporting. However, EPA has concluded that notice of every physical alteration or addition is unnecessary, since many changes have little impact on a permittee's discharge and would create an unnecessary reporting burden. Under the final regulation, EPA will still be kept informed of significant changes to the permitted facility which could result in a permit modification.

One commenter asked that the word "significantly" modify both "change" and "increase." EPA interprets "significantly" to modify both verbs, making such a change unnecessary.

*4. EPA action.* EPA is promulgating the final rule as proposed, with some minor clarifications. The rule will provide the Director with sufficient information for evaluating permit compliance or the need for permit modification, without imposing unnecessary reporting requirements. The second sentence of § 122.41(l)(1) has been split into two sentences to clarify Agency intent that the toxics notification under § 122.42(a) [CPR § 122.61(a)] and reporting on pollutants limited in the permit are separate requirements that do not depend on a significant change in the nature of or increase in the quantity of pollutants discharged. EPA has also added a sentence to clarify the Agency's intent that any change to the permitted facility which may result in a new source must be reported to the Director, allowing him to make a new source determination. Without such notice EPA may not become aware of changes to an existing facility which would be subject to new source performance standards.

EPA has also deleted "For NPDES permittees," since under the deconsolidated regulations this provision only applies to NPDES permittees. Finally, the reference to § 122.42(a)(1) [CPR § 122.61(a)(1)] has been changed to reflect the renumbering sequence of the April 1, 1983 deconsolidation.

**N. Signatories to Reports (40 CFR 122.22(b)(2) [CPR § 122.6(b)(2)])**

*1. Existing rules.* Under the NPDES regulations, all reports required by permits, and any other information requested by the Director, must be signed by a principal executive officer of a corporation or a duly authorized representative of the executive officer (§ 122.22(b)(2) [CPR § 122.6(b)(2)]). The authorization may be to either a person occupying a specified position or a named individual having responsibility for the overall operation of the regulated facility or activity. The signatory requirement is intended to ensure that the corporation is legally accountable for the information submitted. The signature on reports or authorization by a principal executive officer provides this accountability.

*2. Proposed rules.* Industry litigants complained that the signatory requirement was overly restrictive. Many companies have environmental managers who have responsibility within the corporation for ensuring compliance with environmental laws. Litigants argued that these managers would best be able to judge the accuracy and completeness of NPDES reports since they are often in charge of the personnel who do the monitoring and sampling. EPA accepted the litigants' contentions and proposed to allow the principal executive officer to authorize an individual or position having overall responsibility for environmental matters for the company to sign reports.

*3. Comments and responses.* All twelve comments received on this proposed revision supported the change. Commenters supported the idea that environmental managers were the most logical persons to sign reports since they are knowledgeable of the subject area. They suggested that the change would contribute to the accuracy of the reports, while ensuring high level attention to the facility's activities. EPA agrees with commenters that environmental managers will, in many cases, have the best knowledge of the company's facility. Since these managers must still have overall environmental responsibility within the company, and since their authorization to sign the report must come from a principal executive officer, the proposal will also ensure corporate responsibility.

Two commenters, citing the preamble discussion of the proposal (47 FR 52075), questioned whether the signatory provision applied to environmental managers at an individual facility within a company. They suggested that if it did not, the regulation should be further modified. The preamble to the proposed regulation did use language which might have implied that individuals with overall responsibility for a particular facility could be delegated authority to sign reports. EPA's intent, however, was to allow authorization only to an environmental manager having overall responsibility within a company. This would not normally include persons or positions that have responsibility for environmental matters at an individual facility, or even an operating division of a large corporation. This is necessary to assure high level corporate knowledge of and responsibility for a corporation's pollution control operations. Even though environmental managers of individual facilities may have greater personal familiarity with the discharging facility, these individuals may not have sufficient authority to direct activities and responsibilities within the corporation or require changes to corporate procedures which guarantee that all necessary actions are taken to assure accurate reports and compliance.

Several commenters advocated that EPA modify the signatory requirements for permit applications to allow a person with the level of responsibility for signing reports to sign the applications. EPA addressed signatories for applications under a separate settlement agreement with industry litigants and promulgated final regulations. A discussion of the issue can be found at 48 FR 39611 *et seq.*, September 1, 1983.

*4. EPA action.* EPA is adopting a final rule equivalent to the proposal. This action is consistent with the Agency's action concerning signatories for permit applications (see § 122.22(a), 48 FR 39611, September 1, 1983) in that EPA intends to relax the burdens of the signatory requirement where adequate responsibility is ensured. However, unlike the revision to application signatory requirements, this rulemaking will allow environmental managers having overall responsibility for a corporation to sign reports if authorized. The less stringent requirement for reports will provide additional relief, but still ensure responsibility.

**O. Bypass (40 CFR 122.41(m) [CPR § 122.60(g)])**

*1. Existing rules.* The NPDES regulations prohibit bypass, which is defined as the intentional diversion of waste streams from any portion of a treatment facility. The regulation thus requires permittees to operate their entire treatment facility at all times. There are, however, exceptions to the strict prohibition on bypass even where effluent limitations may be violated as a result. Bypass may be excused if the bypass was unavoidable to prevent loss of life, personal injury or severe property damage and there were no feasible alternatives to the bypass. The "no feasible alternatives" provision is not satisfied if the permittee could have installed adequate back-up equipment as preventative maintenance or to prevent a bypass which occurred during normal periods of equipment downtime.

The prohibition of bypass applies even where the permittee does not violate permit limitations during the bypass. However, permittees may bypass if they do not exceed effluent limitations and if the bypass was for essential maintenance to assure efficient facility operations.

The bypass provision was intended to accomplish two purposes. First, it excused certain unavoidable or justifiable violations of permit effluent limitations, provided the permittee could meet the bypass criteria. Second, it required that permittees operate control equipment at all times, thus obtaining maximum pollutant reductions consistent with technology-based requirements. Without such a provision, dischargers could avoid appropriate technology-based control requirements.

*2. Proposed changes.* Industry litigants argued that as long as a permittee complies with the effluent limitations in its permit, no further obligations are incurred. These litigants asserted that a decision to bypass treatment equipment is, and should be treated as, a part of the permittee's discretion in selecting how to treat his waste. At most, additional monitoring should be required during these periods of "in compliance" bypassing to assure permit limits are being met. Litigants from the oil and gas industry argued that even a requirement to monitor effluent during a bypass to ensure it was within permit limitations was too difficult and expensive at offshore facilities. They claimed the cost of transporting samples onshore for analysis would be a unique and significant burden on them.

In response to these concerns, EPA proposed to amend the provision prohibiting bypass where the resultant effluent is in compliance with permit limitations. The proposal would allow any bypass which does not cause a violation of permit limitations or other permit conditions. However, to ensure that permit limitations are, in fact, not exceeded during the bypass, the proposed amendment would require permittees to monitor all affected discharge points at the time of any bypass. In response to claims by offshore oil and gas facilities that they had special circumstances, the proposal allowed the Director to waive additional monitoring requirement if the permittee could otherwise demonstrate that effluent limitations will not be exceeded during the bypass.

EPA also proposed to revise the provision that the "no feasible alternatives" condition is not met if the permittee could have installed adequate back-up equipment. The proposal clarified that this provision is not intended to require the installation of back-up equipment in all cases merely because such equipment could prevent the need for a bypass. Rather, backup equipment would be required where the exercise of reasonable engineering judgment indicated that backup equipment was appropriate to prevent bypass during anticipated periods of equipment downtime or preventive maintenance.

*3. Comments and responses.* In general, industry supported the settlement agreement provision, while State environmental offices and environmental groups opposed the proposal. There are two issues involved in this bypass provision. The first is whether bypass should be allowed when no violation of permit effluent limits results. The second is under what circumstances a permittee must install backup equipment to avoid bypasses during periods of equipment downtime or preventive maintenance.

Supporters of the proposal on the first issue claim there is no justification for prohibiting bypasses that do not cause a violation of permit limits. They argued that the November 18 proposal provides more flexibility in operation and maintenance without decreasing water quality and possibly reduces a facility's operating costs. One commenter supported the relaxation arguing that under the existing regulation an industry might have to shut down operations in order to comply with its NPDES permit even though it was meeting its permit limitations.

Commenters opposed to the proposal stated that a bypass of treatment equipment should be allowed only during essential maintenance and unavoidable breakdown periods and/or only under stated conditions upon approval of the Director. To do otherwise, it was argued, might encourage facilities to "experiment" by eliminating certain unit processes in an effort to cut costs, with potentially disastrous impacts. This group of commenters contended that the CWA intended permittees to fully and effectively operate at all times wastewater treatment equipment installed to achieve permit limits. The proposed provision was regarded as negating this requirement to properly operate and maintain wastewater treatment facilities. Several States pointed out that allowing treatment systems to bypass or run at lower efficiencies, as long as effluent limits or water quality standards are met, undermines the concept of technology-based standards and well-run treatment systems.

The only comment on the provision concerning back-up equipment was a request for clarification of what constitutes "reasonable engineering judgment."

The range of comments on this issue and further analysis convinced EPA that the November 18 proposal on bypass needed further refinement.

EPA believes that the restriction on bypasses where permit limits are being met is necessary for several reasons. EPA's effluent limitations guidelines and standards-setting process are predicted upon the efficient operation and maintenance of removal systems. A number of the effluent limitations

guidelines and standards upon which NPDES permits are based do not contain specific limitations for all of the pollutants of concern for the given industry. For example in the aluminum forming industry, toxic metals such as cadmium, nickel, copper, lead, and selenium found in this industry's wastewaters are not specifically regulated. The data available to EPA show that effective control of these pollutants can be obtained by controlling the discharge of the pollutants regulated by the standard (i.e., chromium, zinc, and aluminum) to levels achievable by the model treatment technology upon which the effluent guideline limits are based. Effluent limitations guidelines imposed on the pulp, paper and paperboard industry are based, in part, upon biological treatment and several pollutants of concern are not specifically regulated due to their effective removal of good biological treatment. Resin acids, fatty acids, bleach plant derivatives, and chloroform are found in wastewaters from plants in this industry and are found to be effectively controlled by efficient biological treatment. If bypass of treatment equipment is allowed, there is no assurance that these unlimited pollutants will be controlled, even though those specifically limited still meet permit limitations.

Similarly, permit writers who establish permit limitations based on their best professional judgment (BPJ) generally evaluate the relevant treatment system and often decide that limitations on all pollutants of concern are not necessary. This may be because, as in the effluent limitations guidelines process, it is determined that limitations on only some of the pollutants will provide adequate control of remaining pollutants so long as treatment equipment is properly operated and maintained. This eliminates the need to impose numerous pollutant limitations and corresponding monitoring requirements which are burdensome and costly to the permittee. It may also be that the treatment system will remove some pollutants to de minimis levels or levels which are difficult to accurately detect. Again the permit writer may determine that it is unnecessary to limit such pollutants which properly run treatment systems will remove. If bypasses of treatment equipment are allowed, it is possible that all pollutants of concern will not receive the level of control anticipated in the establishment of permit limitations.

Several commenters raised questions related to the extent of additional monitoring which would be necessary if bypass up to permit limits was authorized. Some disagreed with the need for special treatment for oil and gas facilities. EPA's decision not to change the existing regulations render this issue moot. Nonetheless, the Agency believes it is appropriate to respond to certain comments on the issue. EPA is persuaded that the special provision allowing offshore oil and gas facilities to dispense with monitoring during periods of bypass was unjustified. Very few oil and gas facilities are situated such that it is unusually or unduly difficult and costly to maintain contact with mainland entities. Considering the unlikelihood that other demonstrations of compliance could be adequately made and the potential for serious adverse cumulative impacts from noncompliance by offshore facilities, EPA now believes the special treatment of these facilities was inappropriate.

The second major bypass issue was when back-up equipment is required to prevent bypass. The only comment on the provision was a request for clarification of what constitutes "reasonable engineering judgment." EPA has concluded that the term "reasonable engineering judgment" by its very nature requires a case specific determination and should not be defined in the regulation because of the complex circumstances that arise in individual cases.

*4. EPA action.* Today's final rule differs from the November 18 proposal. EPA is retaining the existing provision which prohibits bypass even if effluent limitations are not exceeded except for essential maintenance to assure efficient operation of the treatment facility. As described previously, bypassing may affect the effective removal of pollutants of concern which may not be specifically limited in the permit, but which are intended to be controlled.

In cases where in-process changes are made to eliminate or reduce pollutants limited in the permit, the permittee has the opportunity to petition the permitting authority to modify the permit limits. In addition, where a permittee wishes to permanently alter his treatment equipment, for example to replace an outdated component with more efficient, cost-effective equipment, a permit modification may be requested. At that time, the permitting authority may review the appropriateness of the request and the potential impacts of any changes to ensure all pollutants of concern continue to be adequately controlled.

Generally, maintenance is that which is necessary to maintain the performance, removal efficiency and effluent quality of the pollution control equipment. However, for purposes of this section, it is necessary to distinguish between maintenance that is "essential" and that which is routine. Further, a distinction must be drawn between what is considered essential maintenance for industrial treatment systems and that for publicly-owned wastewater treatment plants (POTWs). Industrial facilities usually experience periods of nonprocess operation during which the facility operator can carry out the recommended maintenance procedures contained in the operation and maintenance manual for the facility and/or maintenance advised by the design engineer. Maintenance that can be performed during periods of nonprocess operation at an industrial treatment facility is considered to be routine maintenance, not essential maintenance. However, repairs and maintenance that cannot wait until the production process is not in operation would be deemed essential. If, for example, the seal on a valve malfunctions or a pipe bursts during production hours at an industrial facility and the facility operator bypasses that particular unit process in order to perform corrective maintenance, such maintenance would be considered essential. Of course, economic consideration alone would not be sufficient reason to qualify maintenance as essential.

Unlike most industrial facilities, POTWs are required to operate continuously. Therefore, maintenance must normally be conducted while the treatment facility is in operation. In this situation, it is often unavoidable to bypass certain equipment during maintenance. These maintenance activities would generally be classed as essential. However, since POTWs frequently have capacity exceeding normal loadings, maintenance can normally be conducted during periods of lower flow with no loss in treatment plant performance.

Seasonal effluent limitations which allow the facility to shut down a specific pollution control process during certain periods of the year are not considered to be a bypass. Any variation in effluent limits accounted for and recognized in the permit which allows a facility to dispense with some unit processes under certain conditions is not considered bypassing.

The bypass provision covering back-up equipment is promulgated as proposed. EPA believes that the existing provision could be interpreted to require unnecessary auxiliary treatment facilities. Necessary auxiliary facilities are those back-up systems which should have been installed in the exercise of reasonable engineering judgment to prevent a bypass from occurring during normal periods of equipment downtime or preventive maintenance.

**P. Upset Defense (40 CFR 122.41(n), [CPR § 122.60(h)])**

*1. Existing rules.* Several Courts have ruled that since the equipment underlying technology-based limitations is inherently subject to failure for reasons beyond the control of the operator, EPA must allow for upsets in applying these standards. *See Marathon Oil Co.* v. *EPA*, 564 F.2d 1253 (9th Cir. 1977); *FMC Corp.* v. *Train*, 539 F. 2d 973 (4th Cir. 1976). (For a full explanation of applicable case law, see 44 FR 32863, June 7, 1979.) An upset is an exceptional incident in which there is a temporary and unintentional noncompliance with permit effluent limitations because of factors beyond the reasonable control of the permittee (§ 122.41(n)(1)[CPR § 122.60(h)(1)]). For example, a power failure may cause a treatment system not to function, resulting in a permit violation before the facility can halt its discharge. Section 122.41(n) recognizes an upset as an affirmative defense to an enforcement action for violations of technology-based permit limitations. To establish an upset defense, a permittee must notify EPA of its occurrence within five days and, in any enforcement action, must demonstrate the specific cause of the upset and that the violation was beyond the permittee's reasonable control. Since permittees must develop the information necessary to establish the defense at the time of the upset, the demonstration requirements serve to encourage permittees to examine the treatment facility and to take steps to prevent future noncompliance resulting from the cause of the upset.

*2. Proposed changes.* Industry litigants argued that the upset defense should also apply to violations of water quality-based limitations, since compliance with these standards also depends upon technology. EPA proposed a change to extend the upset defense to permittees that violate water quality-based permit limitations. The proposal would require the permittee to demonstrate that instream water quality standards were achieved in all stream segments, and for all parameters that could have been affected by the discharge. EPA explained that it was not required to provide an upset defense for water quality standards, since the CWA requires strict compliance with water quality standards, regardless of the efficiency of treatment technology. Nevertheless, EPA reasoned, there was no reason to penalize a discharger that can prove the occurrence of an upset if water quality standards were met despite noncompliance with permit requirements.

EPA also proposed to modify the requirement that permittees demonstrate the specific cause of the upset. Litigants were concerned that identification of specific causes would make the defense useless in many cases. To prevent an overly literal application of this requirement that might require a discharger to produce a scientifically impossible level of proof, EPA proposed to delete the word "specific."

*3. Comments and responses.* A number of commenters supported the proposal, stating that dischargers should not be penalized for an upset that violates water quality-based permit limits, but not water quality standards. Another commenter supporting the proposal stated that EPA should not require permittees to demonstrate that water quality standards were maintained throughout the upset. Several other commenters questioned the feasibility of implementing the proposal and, in particular, whether it would be possible for permittees to make the required demonstration.

After reevaluating the proposal in light of the comments on implementation, it is apparent that it is not practical to extend the upset defense to violations of water quality-based limitations. Failures of pollution control equipment can occur on water quality limited stream segments. However, water quality standards are established to protect uses of the water, and are legally required to be met all times. See CWA section 310(b)(1)(C). Any defense for upsets must ensure that water quality standards are achieved at all times throughout the upset. The proposal to establish an upset defense in permits, consistent with the CWA emphasis on protection and enforcement of water quality, would require a showing that water quality standards continued to be achieved in all stream segments, and for all pollutants, potentially affected by the discharge. Permittees would be required to begin monitoring the receiving waters as soon as the upset occurred and to continue to monitor until it was certain that the upset could no longer cause a violation of the water quality standards in the stream segment. To establish the defense, permittees would need to do continuous monitoring on all stream segments that may be affected. If permittees were unable to perform such monitoring, they would be unable to use the defense.

Although the proposal would seemingly allow permittees to claim an upset defense, the costs, burdens, and technical difficulty of establishing that water quality standards were not violated would make the defense nearly impossible for permittees to establish. Since upsets are by definition unexpected, gaps in monitoring would inevitably occur at the onset of the upset condition. Gaps in the monitoring record could create uncertainty as to whether the permittee had complied with water quality standards at all times. In addition, questions could arise as to whether the permittee had monitored all appropriate stream segments. Monitoring and analytical costs for permittees trying to establish an upset defense are likely to be very high for all but minor upsets (for such upsets, EPA is likely to use its enforcement discretion anyway).

Since it would be almost impossible for a permittee to establish the upset defense, the proposed extension would be illusory; adding a provision to the regulations that suggests the existence of such a defense would merely create confusion. This does not mean that dischargers will be penalized whenever an equipment failure that is not within the operator's control occurs. EPA will continue to evaluate such discharges on a case-by-case basis and use its discretion in deciding whether to bring an enforcement action. This approach is more realistic than allowing an affirmative defense for upset that for most purposes cannot be substantiated by the requisite showing for water quality standard protection.

Several States opposed the proposal, suggesting that for violations of water quality-based permit limitations, the NPDES permitting authority should exercise its discretion to determine whether an upset was justifiable. One State went further to suggest that the entire upset provision be deleted and that enforcement discretion should be applied to all permit violations, with permittees left to establish their own defense. For upsets that result in violations of technology-based standards, EPA believes the upset provision is a more reasonable approach which is fully consistent with all legal opinions on the issue. Although most courts have concluded that EPA could rely on its enforcement discretion and need not provide a formal upset provision, EPA continues to believe that

all parties will benefit from allowing permittees an opportunity to present their claims in a formal judicial proceeding. The upset provision also comports with those decisions which have required some form of upset relief. (For a more thorough discussion of applicable case law, see 44 FR 32863 (June 7, 1979)). However, EPA agrees that reliance on enforcement discretion is best with respect to violations of water quality-based permit limitations.

Several persons commented on the proposed deletion of the word "specific" from § 122.41(n)(3)(i) [CPR § 122.60(h)(3)(i)]. Most supported the proposal, but one suggested the change was unnecessary. EPA believes the clarification is desirable since it will eliminate confusion over the meaning of § 122.41(n)(3)(i). This revision clarifies that the regulation does not require investigation to an impossible degree of certainty. For example, there may be cases where biological activity is disrupted in a treatment system, where no change in raw waste characteristics could be identified, and where a thorough investigation by the permittee could not identify the precise cause of the change resulting in the violation. Such evidence could be adduced to show the "cause" required by the regulation, even though the precise cause eluded detection.

EPA would also like to clarify whether a demonstration of "cause" of an upset required under § 122.41(n) can be based upon circumstantial evidence rather than direct evidence. It is EPA's intent that any demonstration of cause acceptable as proof of fact in court be available to a permittee seeking to utilize the upset defense. Proof of fact may be made through circumstantial as well as direct evidence. Indeed, circumstantial evidence may be all that is available. However, it is not enough simply to show that normal operating procedures were followed at the time effluent limitations were exceeded. The regulation requires at least a thorough investigation of the causes of an incident. Obviously, a claim of upset will be disfavored where previous violations have occurred and no efforts or insufficient efforts were made to identify and remedy the cause or causes.

One commenter felt that the upset defense should be available without limitation to all water quality limited dischargers in order to be consistent with the Agency's proposal of October 29, 1982 to revise regulations governing the adoption of water quality standards. The Agency has since promulgated water quality regulations different from the October 29, 1982 proposal (see 48 FR 51400 *et seq.*, November 8, 1983).

*4. EPA action.* In view of the comments, we have reevaluated the proposed revisions to § 122.41(n) and decided to retain the existing regulations, except for the minor clarifying revision to the requirement that permittees demonstrate the cause of an upset (§ 122.41(n)(3)(i)). The affirmative defense of upset will thus only apply to violations of technology-based permit limitations. The upset defense is not available to permittees for violations of water quality-based permit conditions. EPA will rely on prosecutorial discretion and the facts surrounding the upset to determine whether to institute an enforcement action in any such case.

**Q. Proper Operation and Maintenance (40 CFR 122.41(e) [CPR § 122.7(e)])**

*1. Existing rule.* The existing regulations require all permittees to properly operate and maintain their treatment systems. The regulations provide several specific examples of proper operation and maintenance (O & M). This gives permittees notice of their responsibilities and gives permit authorities an additional enforcement tool when permittees are negligent. The ultimate objective is to reduce pollution by ensuring that treatment facilities operate at maximum efficiency.

*2. Proposed changes.* Industry litigants challenged these regulations on the grounds that their specificity improperly infringed upon internal plant management. They also were concerned with language stating that backup equipment must be properly operated and maintained could be interpreted to require such equipment in all cases. In response, EPA proposed to delete most of the specific examples of proper O & M and to clarify that this provision did not impose a requirement to install backup equipment. The proposed deletion of the examples was not intended to remove any obligation of the permittee to properly operate and maintain its treatment equipment but rather to provide greater flexibility to ensure that this is done. The backup provision would still require *available* backup systems to be properly operated and maintained.

*3. Comment and responses.* Six comments were received on this proposal. Five comments were from industry and supported the change, generally citing the litigants' concerns discussed above. One State agency objected to the proposal on the grounds that it gave too much discretion to the permittee to decide what constitutes proper O & M, and stated that backup systems could be reasonably required in some cases. With regard to this comment, EPA has concluded that flexibility is justified and that the proposal still provides adequate environmental protection. The change is not meant to imply that the examples in the existing regulations are no longer considered elements of proper O & M. Permittees remain accountable for any O & M failings, as determined by the permitting authority, even if they occur in those areas deleted from the current regulations. With regard to the comment that installing backup equipment may often be reasonable, EPA agrees and emphasizes that such installation may still be required on a case-by-case basis by the permitting authority. Permit writers are also encouraged to be specific in formulating proper O & M requirements in the permit, especially where poor or inadequate O & M practices have caused problems in the past. This should help to avoid disputes later as to the degree of discretion allowed the permittee.

*4. EPA action.* The proposal does not restrict the permitting authority either in taking action for improper O & M or from requiring backup equipment to be installed on a case-by-case basis. It merely deletes certain examples of proper O & M and makes clear that installation of backup equipment is not a universal requirement. The final regulation is therefore promulgated as proposed.

**R. Mistake and Failure of Technology To Meet Best Professional Judgment (BPJ) Limits as Grounds for Permit Modification (40 CFR 122.62(a) (16), (17) [CPR § 122.15(a)(5)])**

1. *Existing rules.* The current regulations provide limited causes for modifying a permit during its term. These causes do not include as grounds for permit modification either correction of mistakes made at the time of permit issuance or failure of technology on which effluent limits were based to achieve the effluent limitations imposed in a best professional judgment (BPJ) permit. Under the current regulations, a permittee would have no immediate redress for BPJ permit limitations which appropriate, properly installed and operated treatment technology could not meet. A permittee would have to wait until its permit expired and was renewed before it could become eligible for different effluent limitations. In the case of technical mistakes, such as errors in calculations, or mistaken interpretations of law, the permittee would have no redress under the existing regulation expect to correct

typographical errors. The Agency's anti-backsliding policy (§ 122.44(1) [CPR § 122.62(1)]) would prohibit reissuing a permit with less stringent limitations (See discussion in Part C, above).

*2. Proposed changes.* Industry parties to the settlement agreement were concerned that permittees may remain in violation of their permits for years before a change of effluent limitations could be obtained in a renewed permit. They were also concerned that technical mistakes could never be corrected since a reissued permit would be required to be as stringent as the original BPJ permit under the Agency's anti-backsliding policy. In response to this concern, EPA proposed to make both mistaken permit conditions and failure of technology to achieve BPJ limitations causes for permit modification.

*3. Comments and responses.* We received six comments on this proposal; all from industry and all favorable. In general, commenters stated that it was practical and fair for EPA to allow permits to be modified when mistakes are discovered and when properly installed and operated technology required by the permit fails to meet BPJ limitations.

One commenter requested that water quality-based permits be allowed to be modified when there has been a failure of approved technology. This commenter proposed that such a modification of the permit should only be effective until the water quality standards can be reconsidered by the appropriate agency.

Water quality standards are developed by the States, and issued, after approval by EPA, to protect designated uses for particular water bodies or streams. NPDES permits must include water quality-based limitations where the applicable technology-based limitations, whether derived from effluent limitation guidelines or on a BPJ basis, are not stringent enough to ensure compliance with the applicable water quality standards. At the point water quality standards are implemented in the permit issuance process, permit writers do not have the flexibility to reconsider the water quality standards to determine whether they are appropriate or technically achievable. To authorize the modification of an NPDES permit on the basis of BPJ considerations so that it no longer ensures compliance with existing water quality standards clearly cannot be allowed. In addition, to grant the permittee's request pending reconsideration of the water quality standards would result in a de facto change to the standards that is neither within EPA's authority nor appropriate. Rather, the commenter's request should be dealt with in the State's standard setting process. Where a change has been agreed upon by the State, and approved by EPA, provisions for modifying an NPDES permit have already been provided for in the NPDES regulations at 40 CFR 122.62(a)(3) [CPR § 122.15(a)(3)].

One commenter was particularly concerned that the preamble discussion of the proposal drew an overly restrictive interpretation of the types of mistakes which would be grounds for permit modification. This commenter was especially concerned about permits written for new facilities well in advance of start-up and operation. The commenter urged that new information obtained about the particular situation surrounding a discharge be grounds for permit modification. The NPDES permit regulations already provide for permit modification in the event new information, which was not available at the time the permit was issued, is obtained after permit conditions have been established and where the information would have justified the inclusion of different limits at the time the permit is issued. See § 122.62(a)(2) [CPR § 122.15(a)(2)]. This cause adequately provides for permit modification in the circumstances reported by the commenter. However, if the permit was based on a promulgated new source standard, the permittee would be unable to obtain a permit modification (See Anti-backsliding discussion).

*4. EPA action.* As stated in the preamble to the proposal, whether a mistake results in overly lenient or overly stringent permit conditions, it makes sense to authorize permit modifications to correct the mistake. It also makes sense to modify permit conditions when the treatment technology upon which BPJ effluent limitations are based has been properly installed and operated but nonetheless fails to meet those limitations. In both cases, EPA acknowledges that it is unfair to force a permittee to remain in violation until the permit expires and is renewed. The change will allow EPA to correct earlier errors in permit conditions, such as the inclusion of incorrect compliance dates. The final regulation is promulgated as proposed.

### S. Non-adversary Panel Procedures (40 CFR Part 124, Subpart F)

The Administrative Procedure Act (APA) allows decisions on the initial grant of a license or variance to be made by procedures less adversarial than traditional court room procedures, even where a formal hearing is required. Hearings on initial licensing are exempt from formal evidentiary hearing requirements for a number of reasons, most importantly because the complex policy decisions in initial licensing are more akin to rulemaking than adjudication. Additionally, initial licensing decisions do not involve accusation of wrongdoing and, therefore, do not require "separation of functions" within the agency or an initial decision by a statutorily independent individual, such as an administrative law judge (ALJ).

EPA's non-adversary panel procedures for initial licensing were originally promulgated for the NPDES program on June 7, 1979, and revised to include other permit programs on May 19, 1980. Conceived as an innovative and efficient means of resolving disputed scientific and technical issues, these procedures depart from traditional evidentiary procedures in which adversaries present separate cases to an ALJ on a challenge to a final permit decision. Under the non-adversary procedures, participants present their views and arguments to a panel of EPA experts during a two-phased hearing on a draft permit. During the "legislative" phase, the panel explores issues and asks questions. Cross-examination can be ordered during the "adjudicative" phase if certain threshold conditions are met. After the hearing, the panel prepares a recommended decision which may be appealed to the Administrator, whose decision constitutes final agency action subject to judicial review.

*1. Applicability of panel hearing procedures to initial licensing permits and variances (40 CFR 124.111).—a. Existing rules.* Non-adversary panel procedures are not mandatory. The current regulations grant the Regional Administrator the option to use either these procedures or traditional evidentiary hearing procedures for initial licensing and first grants of a variance. We acknowledge that panel hearings may not always be suitable for initial decisions, especially if the factual issues involved make the decisionmaking more akin to adjudication than to rulemaking. For these reasons, EPA made the decision to make use of non-adversary procedures dependent upon the discretion of the Regional Administrator.

*b. Proposed changes.* Industry litigants objected in general to the concept of non-adversary panel procedures, claiming that the procedures violate the formal hearing requirement of the Clean Water Act, that variance decisions do not constitute initial licensing, and that Congress never

intended the initial licensing section of the APA to apply to sharply contested issues of fact such as in NPDES permit proceedings. Specifically, litigants objected to the Regional Administrator's unilateral ability to invoke non-adversary procedures. EPA disagreed with industry's legal arguments and maintained its position that panel procedures are legal and provide an efficient, expeditious means of resolving technical and scientific issues. However, persuaded that panel hearings might not prove useful if invoked upon unwilling participants, EPA proposed that permit applicants must consent to the Regional Administrator's decision to use the panel procedures.

*c. Comments and responses.* EPA received eight comments on this issue, all favorable to the proposal. Some commenters repeated claims of illegal procedures and violations of procedural due process. EPA is unpersuaded by these legal arguments and continues to believe that non-adversary panel procedures for an initial grant of a permit or variance are authorized by the APA. (See 44 FR 32887–32891, June 7, 1979, for more detailed discussion of EPA's legal opinion.) Other commenters endorsed the non-adversary panel procedures, citing cost effectiveness, quicker permitting, better informed presentation of technical issues, and greater opportunity for public participation as the advantages of panel hearings. Nonetheless, they felt that use of such procedures should only be with the consent of the applicant.

*d. EPA action.* Based in part on an analysis of the legal arguments submitted by commenters and on a reevaluation of the role of panel hearings, EPA has decided to retain the regulation in its current form. Non-adversary panel procedures do not restrict the rights of applicants for first grants of permits or variances, and, therefore, the Agency considers it inappropriate to grant such applicants the authority to veto the informed decision of a Regional Administrator to convene a panel hearing. There is no evidence at all that Regional Administrators have invoked or will invoke panel hearings in inappropriate situations. Regional Administrators are in a better position than permit or variance applicants to decide whether certain procedures will aid decisionmaking or expedite permit issuance. For this reason, the sole authority to invoke the non-adversary panel procedures should remain with the Regional Administrator.

*2. Role of panel members in panel hearings (40 CFR 124.120).—a. Existing rules.* As stated above, the APA exempts from initial licensing a number of evidentiary hearing requirements, including the concept of "separation of functions" within the agency. This allows initial licensing decisions to be "institutional" rather than adjudicatory and allows EPA to draw on the training and experience of a number of agency employees, including persons who participated in developing the draft permit. The current EPA regulations restrict the number of permit writers on a panel and require that there be at least two panel members who did not participate in developing the draft permit.

*b. Proposed changes.* Industry parties to the settlement agreement objected to permit writers as panel members on the grounds that it deprives permit applicants of any independent review of the draft permit by the agency, and violates the hearing requirements of the APA. In response to industry's objections, EPA proposed to limit panel members to EPA employees who did not participate in developing the draft permit. As stated in the preamble to the proposal, EPA disagrees with industry's legal arguments on this issue, but proposed the change to avoid the appearance of unfairness.

*c. Comments and responses.* Comments received on this issue supported the proposal to exclude permit writers as panel members.

*d. EPA action.* The final regulation is promulgated as proposed.

*3. Scope of cross-examination (40 CFR 124.121 (a), (b)).—a. Existing rules.* The existing regulations allow cross-examination in a non-adversary panel hearing solely on factual issues. (See § 124.121(a).) The regulation was intended to limit the scope of cross-examination on non-factual issues, since these issues can be better resolved through oral arguments and written presentations. See 44 FR 32886, June 7, 1979.

*b. Proposed changes.* Litigants were concerned that the limitations would prevent cross-examination on factual issues related to policy decisions. EPA, therefore, proposed to relax the restriction and allow cross-examination on policy questions, but only to the extent required to disclose the factual basis for the permit requirements. The proposal was intended to clarify that all factual judgments are eligible for cross-examination, whether or not they are related to policy judgments.

*c. Comments and responses.* All comment received supported EPA's proposal. Several commenters argued that there is no basis for treating cross-examination in panel and evidentiary hearings differently. EPA disagrees with this view. The APA allows decision on the grant of an initial license or variance under procedures less adversarial than either courtroom or formal evidentiary hearings. Non-adversary panel hearings are initial licensing proceedings within the APA. However, while the law allows for different limitations on cross-examination, EPA believes it is reasonable to allow limited cross-examination on policy issues where necessary to resolve material factual issues.

*d. EPA action.* The final regulation on the scope of cross-examination is promulgated as proposed. The new regulation will extend to panel hearings the scope of cross-examination provisions now applicable to evidentiary hearings (§ 124.85(b)(16)). The regulation provides in § 124.121(b) (and in § 124.85(b)(16)), that no cross-examination shall be allowed on questions of policy except to the extent required to disclose the factual basis for permit requirements. This does not preclude cross-examination on facts which form the basis for EPA policy, if such cross-examination relates to the factual basis for permit requirements. Thus, for example, if it were EPA policy to require a specified frequency of monitoring for dischargers of certain pollutants, and if a permittee challenged such a proposed monitoring requirement in a permit subject to a hearing, the permit applicant would be allowed to cross-examine a witness on the factual basis for the required monitoring frequency or why the policy was applied to the applicant's situation. The witness (or EPA counsel) would not be able to terminate the examination simply by answering that the required frequency was EPA "policy."

**T. Evidentiary Hearing Procedures**

*1. Obligation to submit evidence and raise issues (40 CFR 124.13, 124.14, 124.76).—a. Existing rules.* The current regulations require all reasonably ascertainable issues to be raised and available arguments and supporting information to be submitted during the public comment period on a draft permit. If not raised or submitted during the public comment period, this information will not be allowed to be introduced in an evidentiary hearing without good cause. The purpose of these procedures is to encourage resolution of issues at the time comments are submitted on a draft permit, rather than in the far more burdensome context of an evidentiary hearing, and to link that hearing directly

to the preceding stages of permit issuance.

*b. Proposed changes.* Both environmental and industry litigants objected to these requirements on the grounds that the restriction on when evidence may be submitted conflicted with the formal hearing requirements of the Administrative Procedure Act. As a practical matter, litigants argued that the restrictions force parties to engage in "evidentiary overkill" when they disagree with permit terms at the draft permit stage. In response to these concerns, EPA proposed to require only that all reasonably ascertainable issues and available arguments to be raised during the public comment period. Generally, supporting information would not be required to be submitted during the comment period. Rather, all supporting material and factual grounds would be submitted during the public comment periods only if the Regional Administrator either believes that the permit will be contested or elects to reopen the public comment period. In either case, the Regional Administrator would have to determine that submission of evidence during the public comment period would expedite decisionmaking and therefore, require the upfront submission of supporting material in the public notice. If the Regional Administrator either decides that the permit will not be contested or elects not to reopen the public comment period, submission of supporting material and factual grounds would be allowed during an evidentiary hearing.

*c. Comments and responses.* The six comments EPA received on this proposal were from industry which generally supported the change. The American Petroleum Institute specifically endorsed the language in the preamble to the proposal which stated that Regional Administrators would most likely apply these procedures for submission of all information during the initial comment period primarily for major permits, such as for new factories or nuclear power plants, which are likely to be contested and which will involve complex technical issues.

*d. EPA action.* Based on these comments, the final regulation is promulgated as proposed. Section 124.14(a)(3) authorizes the Regional Administrator to require the submission of all evidence during the initial comment period where it reasonably appears that issuance of the permit will be contested and "collapsing the comment period" (i.e., requiring this information during the comment period) may substantially expedite the decisionmaking process. Collapsing the comment periods in this manner may impose greater burdens on participants in the permitting process. Accordingly, the Regional Administrators should exercise this discretion with care. Also, Regional Administrators are encouraged to consult with permit applicants and other known interested persons before exercising their discretion to collapse the comment periods. Such consultation will tend to ensure that the decision is an informed one.

*2. Ex Parte Communications (40 CFR 124.78(a)(1)).*—a. *Existing rules.* The Administrative Procedure Act (APA) prohibits agency decisionmakers in formal hearings from engaging in *ex parte* discussions of the merits with "interested person outside the agency." 5 U.S.C. 557(d) The APA also contains a "separation of functions" provision which requires that no one involved in "investigative or prosecuting functions" may participate or advise in the decision, recommended decision, or agency review * * *" 5 U.S.C. 554(d). The purpose of both requirements is to safeguard the administrative process and ensure impartial decisionmaking.

The current regulations refer to persons involved in "investigative or prosecuting functions" as members of the "agency trial staff" and, thereby, subject them to the *ex parte* rules during evidentiary hearings. Non-EPA witnesses are subject to *ex parte* prohibitions because they are considered "interested persons outside the agency." Under the current regulations, EPA witnesses in evidentiary hearings are not automatically included as part of the agency trial staff, nor are they considered "interested person outside the agency" for the purposes of *ex parte* communications.

*b. Proposed changes.* Industry parties to the settlement agreement objected to the special treatment afforded to EPA witnesses and claimed that these regulations violated the APA and that EPA's failure to designate its evidentiary hearing witnesses as part of the agency trial staff could result in improper *ex parte* contacts between those witnesses and the decisional body. In response to these concerns, EPA proposed to include as a member of the agency trial staff any EPA employee, consultant or contractor, who is either called as a witness by EPA or assisted in developing the draft permit that is the subject of the hearing. The preamble to the proposal emphasized, however, that EPA does not believe that this step is required by law. As stated in the preamble to the current regulations, witnesses from within EPA are subject to the "separation of functions" provision only if they have performed "investigative or prosecuting" functions. (45 FR 33415, May 19, 1980). However, in order to avoid any appearance of unfairness, EPA proposed the above revision.

*c. Comments and responses.* EPA received three comments on this proposal which were from industry and supported the proposed change.

*d. EPA action.* The final regulation is promulgated as proposed.

**U. Deferral of Hearing on New Source Determination (40 CFR 122.21(k)(4) [CPR § 122.53(h)(4)])**

The Clean Water Act treats new sources differently from existing sources. New sources are subject to new source performance standards (NSPS) promulgated pursant to section 306 which reflect the greatest degree of effluent reduction achievable through the application of best available demonstrated control technology (BADT). Existing sources, on the other hand are subject to different, often less stringent, technology-based effluent limitations, representing either best practicable control technology (BPT) or best available technology (BAT) or best conventional technology (BCT). The issuance of an NPDES permit to a new source may also constitute a major Federal action significantly affecting the quality of the human environment, triggering the environmental impact statement provisions of the National Environmental Policy Act (NEPA). (CWA section 511(c)). For these reasons, the decision of whether a facility is a new source (new source determination) is as important to the discharger as it is to the Agency. If dischargers or third parties disagree with the Agency's decision they may challenge the new source determination in an evidentiary hearing.

*1. Existing rule.* The current regulations allow the Regional Administrator to defer an evidentiary hearing on a new source determination until after a final NPDES permit decision is reached. The purpose of the regulation is to allow EPA to combine challenges to the final NPDES permit decision with challenges on the new source determination, and thus save Agency resources by conducting one evidentiary hearing.

*2. Proposed changes.* Litigants were concerned that deferral of a hearing on the new source determination could lengthen the permitting process and increase their costs if the original decision was changed in the hearing. EPA, therefore, proposed to authorized the Regional Administrator to defer an

evidentiary hearing on a new source determination only if all parties to the hearing agreed. The proposal would recognize that an early new source hearing could benefit the permit applicant by informing him of whether he would have to comply with BAT effluent guideline limitations or the generally more stringent new source performance standards. To defer such a hearing might later subject the applicant to potential additional construction costs to comply with new source requirements. The applicant might also be subject to unreasonable expense and delays caused by a NEPA evaluation, which was begun by EPA and later determined to be unnecessary by the hearing decision.

*3. Comments and responses.* The four commenters on this issue all supported the EPA proposal, noting that the Regional Administrator should not be allowed to defer the new source hearing where any party requested an early hearing. The commenters stated that an early hearing on a new source determination would resolve the important question of what treatment standards the facility must be constructed to meet. Three of the commenters were concerned that a deferred hearing would force the applicant to comply with costly additional new source requirements at the end of the permit issuance process (presumably when the facility plans to begin operation). Two commenters when the facility plans to begin operation). Two commenters also noted that an early hearing would help to resolve EPA's obligations under NEPA, since new sources requiring EPA-issued permits are subject to NEPA environmental review requirements.

EPA agrees that the permit applicant should not have to wait until the end of the permit issuance process for a final determination on whether he will be subject to treatment requirements for existing sources or new sources. Otherwise, there may be cases where the applicant designs a facility to meet requirements for existing sources, and subsequently learns that further costs must be allotted to meet a more stringent new source performance standard before the facility can begin operation. An early hearing on the new source determination would also allow EPA to begin its NEPA review work as early as possible, and to limit possible NEPA delays in issuing the final new source permit. In other cases, the early hearing could avoid the necessity of performing a potentially costly NEPA review.

*4. EPA actions.* EPA is promulgating the final rule as proposed. A timely hearing on the new source determination will provide permit applicants with greater certainty on the applicable treatment requirements, and on the costs to meet these requirements. The rule will also allow EPA to complete any required NEPA review (if the facility is a new source) at an early stage and thus limit delays in permit issuance. It will also resolve whether a facility is prohibited from constructing the source due to EPA's pre-permit construction ban (§ 122.29(c)(4) [CPR § 122.66(c)(4)], See Part C, above). These benefits override any additional burdens on EPA to conduct separate new source and permit hearings.

**V. New Source Criteria (40 CFR 122.29(b) [CPR § 122.66(b)])**

*1. Existing rules.* On May 19, 1980, EPA published criteria for new source determinations (40 CFR § 122.66(b)) under the NPDES program as part of its Consolidated Permit Regulations (45 FR 33290). Under that regulation a discharger would be classified as a new source if it was a new facility, if it totally replaced an existing source, or if the construction at the site of an existing facility changed the nature or quantity of pollutants discharged. The classification of a facility as a new or existing source is important because under the CWA existing sources are subject to best available technology (BAT) and best conventional technology (BCT) requirements, while new sources are subject to the generally more stringent new source performance standards (NSPS) under section 306 of the CWA. This distinction is based on the concept that new facilities have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. Section 122.2 [CPR § 122.66(b)] is intended to ensure that all sources are properly classified.

*2. Proposed changes.* On September 9, 1980, EPA suspended CPR §122.66(b) (1) and (2) (45 FR 59317). This suspension responded to industry criticism that the language of the third criterion (CPR §122.66(b)(1)(iii)) was overly broad and could be interpreted as classifying some structures as new sources that more appropriately should be considered as modifications of existing sources. On the same day, (45 FR 59343), EPA proposed that, in those situations where there was new construction but less than total replacement at existing facilities, the classification decision should be based on the degree to which the constructed facility functions independently of the existing source. The substantial independence test was aimed at ascertaining whether an existing source which undertakes major construction that legitimately provides it with the opportunity to install the best and most efficient production processes and wastewater treatment technologies should be required to meet new source performance standards at that facility. Because EPA had already suspended the rule and proposed a new rule at the same time that settlement negotiations on the Consolidated Permit litigation began, EPA removed the issue from the scope of settlement discussions. However, to combine the two NPDES rulemakings, EPA is adopting the final new source criteria with the balance of the NPDES litigation issues.

*3. Comments and responses.* During the public comment period, EPA received twenty-one comments. Most of the commenters approved of the "substantial independence" test as a means of looking at the functional relationship between the existing facility and new facility.

One commenter suggested that further clarification was needed on the meaning of "substantially independent," and suggested a list of factors that should be considered in making such a determination. EPA agrees that such a clarification would help in making new source determinations. Today's amendment, therefore, adds two factors to be examined in deciding if new processes are substantially independent of existing facilities.

The first factor is the degree of integration of a new process with existing processes. Under this first factor, if the new facility is fully integrated into the overall existing plan, the facility will not be a new source. For example, a plant may decide to improve the quality of a product by installing a new purification step into its process, such as a new filter or distillation column. Such a minor change would be integral to existing operations and would not require the facility to be reclassified as a new source. However, on the other extreme, if the only connection between the new and old facility is that they are supplied utilities such as steam, electricity, or cooling water from the same source or that their wastewater effluents are treated in the same treatment plant, then the new facility will be a new source.

Four commenters argued that if a new process or plan uses existing wastewater treatment equipment, for that reason alone it should not be considered a new source. EPA disagrees with these comments. The legislative history of the CWA indicates that new

source requirements were intended to apply where new construction allows flexibility to incorporate new pollution control technology. The fact that a facility can be constructed to utilize an existing waste treatment plant does not address the issue of whether new technology could have been installed. To allow the use of an existing wastewater treatment system, by itself, to preclude the application of new source requirements would frustrate clear statutory intent.

One of the commenters went further and claimed that EPA had no legal authority to impose new requirements in this situation. The commenter argued that if a new facility's discharge is conveyed to waters of the United States through an existing waste treatment system, this new facility cannot itself be classified as a separate point source under the CWA. This claim is contradicted by language of the Act and by case law. A newly constructed facility can clearly meet the statutory definition of "source," which covers any "building, structure, facility, or installation from which there is or may be the discharge of pollutants" (section 306(a) of the Act). When a similar claim was raised in *Mahelona* v. *Hawaiian Electric Co.*, 9 ERC 1625 (D. Hawaii 1976), the Court held that the point source was the facility generating the discharge, not the system treating it.

The second clarifying factor that EPA has added is the extent to which the construction results in facilities or processes that are engaged in the same general type of activity as the existing source. Under this second factor, if the proposed facility is engaged in a sufficiently similar type of activity as the existing source, it will not be treated as a new source. For example, if a plant begins to produce a new product, e.g., nylon synthetic fiber, which is very similar to the product currently being produced by that plant, e.g., polyester synthetic fiber, using equipment that is essentially the same as the existing production equipment, this would likely be considered an existing source. However, if a plant producing a final product, e.g., polyester synthetic fiber, adds new equipment to produce the raw materials for that product, e.g. teraphtalic acid or ethylene glycol, the proposed structure would likely constitute a new source. Of course, to the extent the construction results in facilities engaged in the same type of activity because it essentially replicates, without replacing, the existing source, the new construction would result in a new source.

The proposed regulation provides that if there is no independently applicable new source performance standard a source being classified as a new source under this section would be considered a new discharger. Several industry commenters, all of whom are parties to the litigation, questioned EPA's authority for the new discharger category. EPA continues to believe that EPA has authority to establish the new discharger classification. By such classification EPA is not requiring new dischargers to meet new source performance standards. EPA has merely devised appropriate procedural and substantive requirements for issuing a discharger its first NPDES permit. (See also amendments to the new discharger definition—48 FR 39619, September 1, 1983.)

One commenter further argued that a new facility at the site of a plant in existence before October 18, 1972, could never fit the definition of "new discharger" because there will have been discharges from the existing plant at the site prior to October 18, 1972. This comment misinterprets the definition of "new discharger" in § 122.2 [CPR §122.3]. A new discharger includes a new facility at any site at which "it," the *new facility*, had not discharged pollutants before October 18, 1972; the fact that there may have been discharges from another facility at that same site is irrelevant.

Several commenters suggested that EPA should consider whether the new facility *actually* operates substantially independently of the existing facility, not whether it *could* operate substantially independently, as stated in the preamble to the September 9, 1980 proposal (45 FR 59344). EPA agrees with this interpretation and will so apply the substantial independence test. Because language suggesting a contrary interpretation appeared in the preamble to the proposed rule, no change in the regulatory language is necessary. The test in § 122.29(b)(1)(iii) [CPR § 122.66(1)(iii)] will continue to be whether the processes of the new facility *are* substantially independent.

One commenter suggested that "totally independent" should be substituted for "substantially independent." EPA disagrees with this comment, since it could be argued that any new building, structure, facility, or installation at the same site as an existing facility has some *de minimis* relation to that existing facility.

Some commenters suggested that modernization by means of total replacement of process or production equipment should not result in a new source determination unless it results in the discharge of significant new pollutants. EPA disagrees. Total replacement effectively involves the construction of a new facility, which Congress intended to make subject to new source requirements. An entirely new plant built at the site of an existing plant it totally replaces is no less a new source than the same plant built at a greenfield site, and should be required to build in new source treatment technology.

In a similar situation, if a facility replicates an existing facility, the fact that it shares or uses common land with another source does not prevent it from being considered a new source. The same criteria would be applied on a case specific basis. Thus, if a power company builds a new, but identical and completely separate power generation unit at the site of a similar existing unit, the new unit will be a new source. However, if a facility increases capacity merely by adding additional equipment in one or two production steps to remove a "bottleneck," it will not be a new source. For example, a plant which uses a four step process to convert ethylene oxide into ethylene glycol may increase capacity by installing additional equipment in steps 1 and 3. Such an expansion is likely to be a modification of the existing plant.

One commenter suggested that the phrase in proposed § 122.66(b)(1)(iii), "and it meets the definition of new source in [§ 122.2 [CPR §122.3]]," should more clearly modify all three items under (b)(1). EPA agrees and has placed this phrase at the beginning of (b)(1). This commenter also suggested that the two sentences beginning "A source meeting * * *" be made a separate paragraph (b)(2), with the succeeding paragraphs of (b) renumbered. EPA also agrees with this reformatting and has so amended the regulation. The NPDES new source criteria will apply to all industries where new source performance standards have been proposed or promulgated, except where new source definitions or criteria are otherwise specified in the industry effluent limitation guideline regulations. At the present time only two industries have such specific criteria—(1) the definition of new source in the wet process hardboard subcategory of the Timber Products effluent limitations guideline (See 46 FR 45382, October 13, 1982); and (2) the criteria for new source determinations in the Coal Mining effluent limitations guideline (See 46 FR 8260, January 26, 1981).

*4. EPA action.* In the final rule, EPA has retained the proposed substantially

independent test to ascertain whether construction at the site of an existing source, which does not involve total replacement of process or production equipment, would result in a new source. EPA has clarified this test by adding the following factors which should be considered in making the determination of whether construction at an existing facility results in processes that are substantially independent and therefore qualify as a new source: (1) The extent to which the new facility is integrated with the existing plant; and (2) the extent to which the new facility is engaged in the same general type of activity as the existing source.

**W. Modification of NPDES Permits (40 CFR 122.62, 122.63 [CPR §§ 122.15, 122.17])**

*1. Existing rules.* The NPDES permit regulations specify causes for permit modification. In general, permits are not modified to incorporate changes made in regulations during the term of the permit. This is to provide some measure of certainty to both the permittees and the Agency during the term of the permits. Thus, the changes made in today's final promulgation of regulations, with few exceptions, do not affect or provide cause for modification of existing permits. Permittees must comply with the terms of their permits, even if those terms might be different than the requirements of subsequent regulations. See CWA section 402(k).

*2. Proposed changes.* Industry litigants were concerned that current regulations would preclude modification of permits to incorporate changes made by today's regulations. Thus, in order to allow current permittees to benefit from today's final rules, EPA proposed to add a new subsection to § 122.62 [CPR § 122.15] allowing NPDES permits that became final after March 9, 1982, to be modified to conform to the final rules concerning bypass, actual production, total metals, and discharge into POTWs, wells, or by land disposal. (Specific discussions on each of these final rules appear above.) In order to prevent the administrative burden that would result if all currently issued permits were eligible for modification, EPA proposed to allow modification only for permits issued after March 9, 1982, and limited those provisions for which modification was available. Otherwise, permit modifications would create a severe administrative burden and divert Agency resources better spent in reissuing permits.

A permittee seeking modification would be required to demonstrate that it qualifies for the modification and that good cause exists to modify the permit. A permittee would also have to request modification within 90 days of the issuance of a final rule. The good cause requirements calls for the permittee to show something more than that it qualifies for the modification since such a showing must be made in any modification request. For example, the permittee might show good cause by demonstrating that the modification would result in cost savings, reduce energy consumption, allow the use of simpler or more reliable control technologies, or otherwise significantly alleviate the burdens imposed by its current permit terms and conditions, including permit limits.

EPA also proposed to add a new subsection to § 122.63 [CPR § 122.17] allowing modifications to incorporate certain newly modified provisions to be processed as minor permit modifications. These provisions are: proper operation and maintenance, planned facility change, bypass, upset, and toxics notification. (For specific discussions on each of these, see above.) Changes to a permit to reflect these revised rules could, under that proposal, be processed through the streamlined minor modification procedure which does not require public notice and comment. These provisions do not require recalculation of permit limits; they merely add boilerplate language to the permit. Therefore, full notice and opportunity for comment and public hearings on the changes to a specific permit are not essential. The notice and opportunity for comment on today's final rule have provided for adequate public participation on these provisions.

*3. Comments and responses.* Five comments were received on the modification of NPDES permits portion of the proposal. The commenters supported the proposal because it was believed it would prevent unnecessary applications for evidentiary hearings by applicants. The changes were viewed as conserving administrative resources while allowing a greater number of permittees to benefit from EPA's proposed revisions.

One commenter advocated allowing permits to be modified if the existing NPDES permit has been extended pending the issuance of a "second-round" permit; or if the permit is currently the subject of an enforcement proceeding which would be rendered moot by today's revisions; or if the permit has been subject to noncompliance problems which would be eliminated by today's revisions.

Permits which have "expired" cannot be modified. While expired permits may be continued in effect beyond the permit terms under the Administrative Procedure Act and § 122.6 [CPR § 122.5], these permits may only be changed by reissuance. The other two situations advocated by the commenter concern violations of existing regulations or permit conditions. To allow broad retroactive application of permit revisions thereby rendering moot enforcement and noncompliance actions would thwart the intent of the CWA and the NPDES permit regulations. Permit conditions must be met during the term of the permit. And, in the situations described, a violation of permit conditions has occurred and enforcement or noncompliance actions have been deemed warranted. Subsequent changes in the regulation do not change the fact that violations of permit conditions occurred under the applicable regulations.

*4. EPA action.* EPA agrees that the modification of permits to conform to today's regulations is appropriate in order to prevent unnecessary administrative hearings and litigation. The cutoff date precludes unnecessary modifications that could place a strain on Agency or State resources. Therefore, the proposal is adopted in the final regulations. However, since some of the subjects listed in the provisions qualifying for modifications under today's rulemaking are not being changed in accordance with the settlement agreement and instead EPA is retaining the existing regulations, there is no need to provide a cause for modification of permits for those provisions. Section 122.62 covers only actual production and total metals. Section 122.63 covers only operation and maintenance, planned facility change, one specific provision relating to bypasses, and toxics notification.

## III. EFFECTIVE DATE

Section 553(d) of the Administrative Procedure Act (APA) generally requires publication of a substantive rule not less than 30 days before its effective date. The purpose of this requirement is to allow sufficient lead time to prepare for compliance with new regulatory requirements. EPA considers today's rulemaking of sufficient complexity and import that the regulations shall not go into effect until October 26, 1984.

## IV. EXECUTIVE ORDER 12291

Under Executive Order 12291, EPA must judge whether a regulation is major and therefore subject to the requirement of a Regulatory Impact Analysis. These amendments generally make the

regulations more flexible and less burdensome for affected permittees. For some provisions they make no change from the existing regulations. These regulations do not satisfy any of the criteria specified in section 1(b) of the Executive Order and, as such, do not constitute major rulemakings. This regulation was submitted to OMB for review.

## V. PAPERWORK REDUCTION ACT

In accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, EPA must submit to the Director of OMB for review and approval, new or revised requirements for collection of information. The amendments promulgated today generally decrease or eliminate requirements for the collection of information. The revised information collection requirements in this rule are not effective until OMB approves them and a technical amendment to that effect is published in the Federal Register.

## VI. REGULATORY FLEXIBILITY ACT

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, EPA is required to prepare a Regulatory Flexibility Analysis to assess the impact of rules on small entities. No regulatory flexibility analysis is required, however, where the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Today's amendments to the regulations generally make the regulations more flexible and less burdensome for permittees. For some provisions they make no change from the existing regulations. Accordingly, I hereby certify, pursuant to 5 U.S.C. 605(b), that these amendments will not have a significant impact on a substantial number of small entities.

### List of Subjects

*40 CFR Part 122*

Administrative practice and procedure, Reporting and recordkeeping requirements, Water pollution control, Confidential business information.

*40 CFR Part 124*

Administrative practice and procedure, Air pollution control, Hazardous materials, Waste treatment and disposal, Water pollution control, Water supply, Indians—lands.

*40 CFR Part 125*

Water pollution control, Waste treatment and disposal.

(Clean Water Act, 33 U.S.C. 1251 *et seq.*)

Dated: September 4, 1984.

**Alvin L. Alm,**

*Acting Administrator.*

1. The heading for Part 122 is revised to read as follows:

## PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

### Subpart B—Permit Application and Special NPDES Program Requirements

1a. Section 122.21 is amended by designating the existing paragraph (c) as (c)(1) and adding new paragraphs (c)(2) and (f)(9), by revising paragraphs (f) (7), (g)(7) introductory text, (g)(7)(i)(B), (g)(7)(iii), (g)(9), (g)(10), and (k)(4) to read as follows:

**§ 122.21 Application for a permit (applicable to State NPDES programs, see §123.25).**

* * * * *

(c) * * *

(2) Any existing storm water discharger under § 122.26 that does not have an effective permit shall submit an application by March 26, 1985. Any discharger designated under § 122.26(c) shall submit an application within 6 months of notification of its designation.

* * * * *

(f) * * *

(7) A topographic map (or other map if a topographic map is unavailable) extending one mile beyond the property boundaries of the source, depicting the facility and each of its intake and discharge structures; each of its hazardous waste treatment, storage, or disposal facilities; each well where fluids from the facility are injected underground; and those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant in the map area. Group II storm water discharges, as defined in § 122.26(b)(3), are exempt from the requirements of paragraph (f) (7) of this section.

* * * * *

(9) For Group II storm water dischargers (as defined in § 122.26(b)(3)) only, a brief narrative description of:

(i) The drainage area, including an estimate of the size and nature of the area;

(ii) The receiving water; and

(iii) Any treatment applied to the discharge.

(g) * * *

(7) *Effluent characteristics.* Information on the discharge of pollutants specified in this subparagraph. When "quantitative data" for a pollutant are required, the applicant must collect a sample of effluent and analyze it for the pollutant in accordance with analytical methods approved under 40 CFR Part 136. When no analytical method is approved the applicant may use any suitable method but must provide a description of the method. When an applicant has two or more outfalls with substantially identical effluents, the Director may allow the applicant to test only one outfall and report that the quantitative data also apply to the substantially identical outfalls. The requirements in paragraphs (g)(7) (iii) and (iv) of this section that an applicant must provide quantitative data for certain pollutants known or believed to be present do not apply to pollutants present in a discharge solely as the result of their presence in intake water; however, an applicant must report such pollutants as present. Grab samples must be used for pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, and fecal coliform. For all other pollutants, 24-hour composite samples must be used. However, a minimum of one grab sample may be taken for effluents from holding ponds or other impoundments with a retention period greater than 24 hours, and a minimum of one to four (4) grab samples may be taken for storm water discharges depending on the duration of the discharge. One grab sample shall be taken in the first hour (or less) of discharge with one additional grab sample taken in each succeeding hour of discharge up to a minimum of four grab samples for discharges lasting four or more hours. In addition, the Director may waive composite sampling for any outfall for which the applicant demonstrates that the use of an automatic sampler is infeasible and that the minimum of four (4) grab samples will be a representative sample of the effluent being discharged. An applicant is expected to "know or have reason to believe" that a pollutant is present in an effluent based on an evaluation of the expected use, production, or storage of the pollutant, or on any previous analyses for the pollutant. (For example, any pesticide manufactured by a facility may be expected to be present in contaminated storm water runoff from the facility.)

(i) * * *

(B) The Director may waive the reporting requirements for individual point sources or for a particular industry category for one or more of the pollutants listed in paragraph (g)(7)(i)(A) of this section if the applicant has demonstrated that such a waiver is appropriate because information adequate to support issuance of a permit

can be obtained with less stringent requirements.

* * * * *

(iii)(A) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants in Table IV of Appendix D (certain conventional and nonconventional pollutants) is discharged from each outfall. If an applicable effluent limitations guideline either directly limits the pollutant or, by its express terms, indirectly limits the pollutant through limitations on an indicator, the applicant must report quantitative data. For every pollutant discharged which is not so limited in an effluent limitations guideline, the applicant must either report quantitative data or briefly describe the reasons the pollutant is expected to be discharged.

(B) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants listed in Table II or Table III of Appendix D (the toxic pollutants and total phenols) for which quantitative data are not otherwise required under paragraph (g)(7)(ii) of this section, is discharged from each outfall. For every pollutant expected to be discharged in concentrations of 10 ppb or greater the applicant must report quantitative data. For acrolein, acrylonitrile, 2,4 dinitrophenol, and 2-methyl-4,6 dinitrophenol, where any of these four pollutants are expected to be discharged in concentrations of 100 ppb or greater the applicant must report quantitative data. For every pollutant expected to be discharged in concentrations less than 10 ppb, or in the case of acrolein, acrylonitrile, 2,4 dinitrophenol, and 2-methyl-4,6 dinitrophenol, in concentrations less than 100 ppb, the applicant must either submit quantitative data or briefly describe the reasons the pollutant is expected to be discharged. An applicant qualifying as a small business under paragraph (g)(8) of this section is not required to analyze for pollutants listed in Table II of Appendix D (the organic toxic pollutants).

* * * * *

(9) *Used or manufactured toxics.* A listing of any toxic pollutant which the applicant currently uses or manufactures as an intermediate or final product or byproduct. The Director may waive or modify this requirement for any applicant if the applicant demonstrates that it would be unduly burdensome to identify each toxic pollutant and the Director has adequate information to issue the permit.

(10) *Storm water point source exemption.*

(i) An applicant that qualifies as a Group II storm water discharger under § 122.26(b)(3) is exempt from the requirements of paragraphs (f)(7) and (g) of this section, unless the Director requests such information.

(ii) For the purpose of paragraph (g)(3) of this section, storm water point sources may estimate the average flow of their discharge and must indicate the rainfall event and the method of estimation that the estimate is based on.

(iii) The Director may require additional information under paragraph (g)(13) of this section, and may request any Group II storm water dischargers to comply with paragraph (g) of this section.

* * * * *

(k) * * *

(4) Any interested person may challenge the Regional Administrator's initial new source determination by requesting an evidentiary hearing under Subpart E of Part 124 within 30 days of issuance of the public notice of the initial determination. If all parties to the evidentiary hearing on the determination agree, the Regional Administrator may defer the hearing until after a final permit decision is made, and consolidate the hearing on the determination with any hearing on the permit.

* * * * *

2. Section 122.22 is amended by revising paragraph (b) introductory text and (b)(2) to read as follows:

**§ 122.22 Signatories to permit applications and reports (applicable to State NPDES programs, see § 123.25).**

* * * * *

(b) All reports required by permits, other information requested by the Director, and all permit applications submitted for Group II storm water discharges under § 122.26(b)(3) shall be signed by a person described in paragraph (a), or by a duly authorized representative of that person. A person is a duly authorized representative only if:

* * * * *

(2) The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity such as the position of plant manager, operator of a well or a well field, superintendent, position of equivalent responsibility, or an individual or position having overall responsibility for environmental matters for the company. (A duly authorized representative may thus be either a named individual or any individual occupying a named position.)

* * * * *

3. Section 122.26 is revised to read as follows:

**§ 122.26 Storm water discharges (applicable to State NPDES programs, see § 123.25).**

(a) *Permit requirement.* Storm water point sources, as defined in this section, are point sources subject to the NPDES permit program. The Director may issue an NPDES permit or permits for discharges into waters of the United States from a storm water point source covering all conveyances which are a part of that storm water discharge. Where there is more than one owner or operator of a single system of such conveyances, any or all discharges into the storm water discharge system may be identified in the application submitted by the owner or operator of the portion of the system that discharges directly into waters of the United States. Any such application shall include all information regarding discharges into the system that would be required if the dischargers submitted separate applications. Dischargers so identified shall not require a separate permit unless the Director specifies otherwise. Any permit covering more than one owner or operator shall identify the effluent limitations, if any, which apply to each owner or operator. Where there is more than one owner or operator, no discharger into the storm water discharge may be subject to a permit condition for discharges into the storm water discharge other than its own discharges into that system without its consent. All dischargers into a storm water discharge system must either be covered by an individual permit or a permit issued to the owner or operator of the portion of the system that directly discharges. (See § 122.21(c)(2) for application deadline for existing storm water point sources.)

(b) *Definitions.* (1) "Storm water point source" means a conveyance or system of conveyances (including pipes, conduits, ditches, and channels) primarily used for collecting and conveying storm water runoff and which:

(i) Is located at an urbanized area as designated by the Bureau of the Census according to the criteria in 39 FR 15202 (May 1, 1974);

(ii) Discharges from lands or facilities used for industrial or commercial activities; or

(iii) Is designated under paragraph (c) of this section. Conveyances that discharge storm water runoff combined with municipal sewage are point sources that must obtain NPDES permits, but are not "storm water point sources".

(2) "Group I storm water discharge" means any "storm water point source" which is:

(i) Subject to effluent limitations guidelines, new source performance standards, or toxic pollutant effluent standards;

(ii) Designated under paragraph (c) of this section; or

(iii) Located at an industrial plant or in plant associated areas. "Plant associated areas" means industrial plant yards, immediate access roads, drainage ponds, refuse piles, storage piles or areas and material or products loading and unloading areas. The term excludes areas located on plant lands separate from the plant's industrial activities, such as office buildings and accompanying parking lots.

(3) "Group II storm water discharge" means any "storm water point source" not included in paragraph (b)(2) of this section. (See § 122.21(g)(10) for exemption from certain apllication requirements.)

(4) A conveyance or system of conveyances operated primarily for the purpose of collecting and conveying storm water runoff which does not constitute a "storm water point source" under paragraph (b)(1) of this section is not considered a point source subject to the requirements of CWA.

(5) Whether a system of conveyances is or is not a storm water point source for purposes of this section shall have no bearing on whether the system is eligible for funding under Title II of CWA. See 40 CFR 35.925–21.

(c) *Case-by-case designation of storm water discharges.* The Director may designate a conveyance or system of conveyances primarily used for collecting and conveying storm water runoff as a storm water point source. This designation may be made to the extent allowed or required by EPA promulgated effluent limitations guidelines for point sources in the storm water discharge category or when:

(1) A Water Quality Management plan under section 208 of CWA which contains requirements applicable to such point sources is approved; or

(2) The Director determines that a storm water discharge is a significant contributor of pollution to the waters of the United States. In making this determination the Director shall consider the following factors:

(i) The location of the discharge with respect to waters of the United States;

(ii) The size of the discharge;

(iii) The quantity and nature of the pollutants reaching waters of the United States; and

(iv) Other relevant factors.

4. Section 122.28 is amended by revising paragraph (a)(2) as follows:

**§ 122.28 General permits (applicable to State NPDES Programs, see § 123.25).**

(a) * * *

(2) *Sources.* The general permit may be written to regulate, within the area described in paragraph (a)(1) of this section, either:

(i) Storm water point sources; or

(ii) A category of point sources other than storm water point sources if the sources all:

(A) Involve the same or substantially similar types of operations;

(B) Discharge the same types of wastes;

(C) Require the same effluent limitation or operating conditions;

(D) Require the same or similar monitoring; and

(E) In the opinion of the Director, are more appropriately controlled under a general permit than under individual permits.

* * * * *

5. Section 122.29 is amended by revising paragraphs (b), (c)(3), and (d)(4), redesignating paragraph (c)(5) as (c)(5)(ii) and adding a new paragraph (c)(5)(i) to read as follows:

**§ 122.29 New sources and new dischargers.**

* * * * *

(b) *Criteria for new source determination.*

(1) Except as otherwise provided in an applicable new source performance standard, a source is a "new source" if it meets the definition of "new source" in § 122.2, and

(i) It is constructed at a site at which no other source is located; or

(ii) It totally replaces the process or production equipment that causes the discharge of pollutants at an existing source; or

(iii) Its processes are substantially independent of an existing source at the same site. In determining whether these processes are substantially independent, the Director shall consider such factors as the extent to which the new facility is integrated with the existing plant; and the extent to which the new facility is engaged in the same general type of activity as the existing source.

(2) A source meeting the requirements of paragraphs (b)(1) (i), (ii), or (iii) of this section is a new source only if a new source performance standard is independently applicable to it. If there is no such independently applicable standard, the source is a new discharger. See § 122.2.

(3) Construction on a site at which an existing source is located results in a modification subject to § 122.62 rather than a new source (or a new discharger) if the construction does not create a new building, structure, facility, or installation meeting the criteria of paragraphs (b)(1) (ii) or (iii) of this section but otherwise alters, replaces, or adds to existing process or production equipment.

(4) Construction of a new source as defined under § 122.2 has commenced if the owner or operator has:

(i) Begun, or caused to begin as part of a continuous on-site construction program:

(A) Any placement, assembly, or installation of facilities or equipment; or

(B) Significant site preparation work including clearing, excavation or removal of existing buildings, structures, or facilities which is necessary for the placement, assembly, or installation of new source facilities or equipment; or

(ii) Entered into a binding contractual obligation for the purchase of facilities or equipment which are intended to be used in its operation with a reasonable time. Options to purchase or contracts which can be terminated or modified without substantial loss, and contracts for feasibility engineering, and design studies do not constitute a contractual obligation under the paragraph.

(c) * * *

(3) The Regional Administrator, to the extent allowed by law, shall issue, condition (other than imposing effluent limitations), or deny the new source NPDES permit following a complete evaluation of any significant beneficial and adverse impacts of the proposed action and a review of the recommendations contained in the EIS or finding of no significant impact.

* * * * *

(5)(i) The commencement of on-site construction in violation of paragraph (c) of this section shall constitute grounds for denial of a permit.

* * * * *

(d) * * *

(4) The owner or operator of a new source, a new discharger which commenced discharge after August 13, 1979, or a recommencing discharger shall install and have in operating condition, and shall "start-up" all pollution control equipment required to meet the conditions of its permits before beginning to discharge. Within the shortest feasible time (not to exceed 90 days), the owner or operator must meet all permit conditions. The requirements of this paragraph do not apply if the owner or operator is issued a permit

containing a compliance schedule under § 122.47(a)(2)

* * * * *

**Subpart C—Permit Conditions**

6. Section 122.41 is amended by revising paragraphs (e), (l)(1), (m)(4)(i)(B), and (n)(3)(i) to read as follows:

**§ 122.41 Conditions applicable to all permits.**

* * * * *

(3) *Proper operation and maintenance.* The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems which are installed by a permittee only when the operation is necessary to achieve compliance with the conditions of the permit.

* * * * *

(l) *Reporting requirements.*—(1) *Planned changes.* The permittee shall give notice to the Director as soon as possible of any planned physical alterations or additions to the permitted facility. Notice is required only when:

(i) The alteration or addition to a permitted facility may meet one of the criteria for determining whether a facility is a new source in § 122.29(b); or

(ii) The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants which are subject neither to effluent limitations in the permit, nor to notification requirements under § 122.42(a)(1).

* * * * *

(m) * * *

(4) * * *

(i) * * *

(B) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and

* * * * *

(n) * * *

(3) * * *

(i) An upset occurred and that the permittee can identify the cause(s) of the upset;

* * * * *

7. Section 122.42 is amended by revising paragraphs (a)(1) introductory text, (a)(1)(iii), and (a)(2) to read as follows:

**§ 122.42 Additional conditions applicable to specified categories of NPDES permits (applicable to State NPDES programs, see § 123.25).**

(a) * * *

(1) That any activity has occurred or will occur which would result in the discharge, on a routine or frequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

* * * * *

(iii) Five (5) times the maximum concentration value reported for that pollutant in the permit application in accordance with § 122.21(g)(7); or

* * * * *

(2) That any activity has occurred or will occur which would result in any discharge, on a non-routine or infrequent basis, of a toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

(i) Five hundred micrograms per liter (500 μg/l);

(ii) One milligram per liter (1 mg/l) for antimony;

(iii) Ten (10) times the maximum concentration value reported for that pollutant in the permit application in accordance with § 122.21(g)(7).

(iv) The level established by the Director in accordance with § 122.44(f).

* * * * * *

8. Section 122.44 is amended by revising paragraphs (d)(3) and (d)(9); by removing paragraph (e)(1)(ii); and by redesignating paragraph (e)(1)(i) as paragraph (e)(1), to read as follows:

**§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).**

* * * * *

(d) * * *

(3) Conform to the conditions to a State certification under section 401 of the CWA that meets the requirements of § 124.53 when EPA is the permitting authority. If a State certification is stayed by a court of competent jurisdiction or an appropriate State board or agency, EPA shall notify the State that the Agency will deem certification waived unless a finally effective State certification is received within sixty days from the date of the notice. If the State does not forward a finally effective certification within the sixty day period, EPA shall include conditions in the permit that may be necessary to meet EPA's obligation under section 301(b)(1)(C) of the CWA;

* * * * *

(9) Incorporate any other appropriate requirements, conditions, or limitations (other than effluent limitations) into a new source permit to the extent allowed by the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.* and section 511 of the CWA, when EPA is the permit issuing authority. (See § 122.29(c)).

* * * * *

9. Section 122.45 is amended by revising paragraphs (b)(2), (c), and (g), deleting paragraph (h), and redesignating paragraphs (i) and (j) as (h) and (i) to read as follows:

**§ 122.45 Calculating NPDES permit conditions (applicable to State NPDES programs, see § 123.25).**

* * * * *

(b) * * *

(2)(i) Except in the case of POTWs or as provided in paragraph (b)(2)(ii) of this section, calculation of any permit limitations, standards, or prohibitions which are based on production (or other measure of operation) shall be based not upon the designed production capacity but rather upon a reasonable measure of actual production of the facility. For new sources or new dischargers, actual production shall be estimated using projected production. The time period of the measure of production shall correspond to the time period of the calculated permit limitations; for example, monthly production shall be used to calculate average monthly discharge limitations.

(ii)(A)(*1*) The Director may include a condition establishing alternate permit limitations, standards, or prohibitions based upon anticipated increased (not to exceed maximum production capability) or decreased production levels.

(*2*) *For the automotive manufacturing industry* only, the Regional Administrator shall, and the State Director may establish a condition under paragraph (b)(2)(ii)(A)(*1*) of this section if the applicant satisfactorily demonstrates to the Director at the time the application is submitted that its actual production, as indicated in paragraph (b)(2)(i) of this section, is substantially below maximum production capability and that there is a reasonable potential for an increase above actual production during the duration of the permit.

(B) If the Director establishes permit conditions under paragraph (b)(2)(ii)(A) of this section:

(*1*) The permit shall require the permittee to notify the Director at least two business days prior to a month in which the permittee expects to operate at a level higher than the lowest production level identified in the permit. The notice shall specify the anticipated level and the period during which the permittee expects to operate at the alternate level. If the notice covers more than one month, the notice shall specify the reasons for the anticipated production level increase. New notice of discharge at alternate levels is required to cover a period or production level not covered by prior notice or, if during two consecutive months otherwise covered by a notice, the production level at the permitted facility does not in fact meet the higher level designated in the notice.

(*2*) The permittee shall comply with the limitations, standards, or prohibitions that correspond to the lowest level of production specified in the permit, unless the permittee has notified the Director under paragraph (b)(2)(ii)(B)(*1*) of this section, in which case the permittee shall comply with the lower of the actual level of production during each month or the level specified in the notice.

(*3*) The permittee shall submit with the DMR the level of production that actually occurred during each month and the limitations, standards, or prohibitions applicable to that level of production.

(c) *Metals.* All permit effluent limitations, standards, or prohibitions for a metal shall be expressed in terms of "total recoverable metal" as defined in 40 CFR Part 136 unless:

(1) An applicable effluent standard or limitation has been promulgated under the CWA and specifies the limitation for the metal in the dissolved or valent or total form; or

(2) In establishing permit limitations on a case-by-case basis under § 125.3, it is necessary to express the limitation on the metal in the dissolved or valent or total form to carry out the provisions of the CWA; or

(3) All approved analytical methods for the metal inherently measure only its dissolved form (*e.g.*, hexavalent chromium).

* * * * *

(g) *Pollutants in intake water.*

(1) Upon request of the discharger, technology-based effluent limitations or standards shall be adjusted to reflect credit for pollutants in the discharger's intake water if:

(i) The applicable effluent limitations and standards contained in 40 CFR Subchapter N specifically provide that they shall be applied on a net basis; or

(ii) The discharger demonstrates that the control system it proposes or uses to meet applicable technology-based limitations and standards would, if properly installed and operated, meet the limitations and standards in the absence of pollutants in the intake waters.

(2) Credit for generic pollutants such as biochemical oxygen demand (BOD) or total suspended solids (TSS) should not be granted unless the permittee demonstrates that the constituents of the generic measure in the effluent are substantially similar to the constituents of the generic measure in the intake water or unless appropriate additional limits are placed on process water pollutants either at the outfall or elsewhere.

(3) Credit shall be granted only to the extent necessary to meet the applicable limitation or standard, up to a maximum value equal to the influent value. Additional monitoring may be necessary to determine eligibility for credits and compliance with permit limits.

(4) Credit shall be granted only if the discharger demonstrates that the intake water is drawn from the same body of water into which the discharge is made. The Director may waive this requirement if he finds that no environmental degradation will result.

(5) This section does not apply to the discharge of raw water clarifier sludge generated from the treatment of intake water.

* * * * *

10. Section 122.47 is amended by revising paragraph (a)(2) to read as follows:

**§ 122.47 Schedules of compliance.**

(a) * * *

(2) The first NPDES permit issued to a new source or a new discharger shall contain a schedule of compliance only when necessary to allow a reasonable opportunity to attain compliance with requirements issued or revised after commencement of construction but less than three years before commencement of the relevant discharge. For recommencing dischargers, a schedule of compliance shall be available only when necessary to allow a reasonable opportunity to attain compliance with requirements issued or revised less than three years before recommencement of discharge.

* * * * *

11. Section 122.49 is amended by revising paragraph (g) as follows:

**§ 122.49 Considerations under Federal law.**

* * * * *

(g) The National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, may require preparation of an Environmental Impact Statement and consideration of EIS-related permit conditions (other than effluent limitations) as provided in § 122.29(c).

12. Section 122.50 is amended by revising paragraph (a)(2) to read as follows:

**§ 122.50 Disposal of pollutants into wells, into publicly owned treatment works or by land application (applicable to State NPDES programs, see § 123.25).**

(a) * * *

(2) In all cases other than those described in paragraph (a)(1) of this section, effluent limitations shall be adjusted by multiplying the effluent limitation derived by applying effluent limitation guidelines to the total waste stream by the amount of wastewater flow to be treated and discharged into waters of the United States, and dividing the result by the total wastewater flow. Effluent limitations and standards so calculated may be further adjusted under Part 125, Subpart D to make them more or less stringent if discharges to wells, publicly owned treatment works, or by land application change the character or treatability of the pollutants being discharged to receiving waters. This method may be algebraically expressed as:

$$P = \frac{E \times N}{T}$$

where P is the permit effluent limitation, E is the limitation derived by applying effluent guidelines to the total wastestream, N is the wastewater flow to be treated and discharged to waters of the United States, and T is the total wastewater flow.

* * * * *

## Subpart D—Transfer, Modification, Revocation and Reissuance, and Termination of Permits

13. Section 122.62 is amended by removing paragraph (a)(12), redesignating paragraphs (a) (13), (14), and (15) as (a) (12), (13), and (14) respectively and adding new paragraphs (a) (15), (16), (17), and (18) to read as follows:

**§ 122.62 Modification or revocation and reissuance of permits (applicable to State NPDES programs, see § 123.25).**

(a) * * *

(15) When the permittee's effluent limitations were imposed under section 402(a)(1) of the CWA and the permittee demonstrates operation and maintenance costs that are totally disproportionate from the operation and maintenance costs considered in the development of a subsequently promulgated effluent limitations guideline, but in no case may the limitations be made less stringent than the subsequent guideline.

(16) To correct technical mistakes, such as errors in calculation, or mistaken interpretations of law made in determining permit conditions.

(17) When the discharger has installed the treatment technology considered by the permit writer in setting effluent limitations imposed under section 402(a)(1) of the CWA and has properly operated and maintained the facilities but nevertheless has been unable to achieve those effluent limitations. In this case, the limitations in the modified permit may reflect the level of pollutant control actually achieved (but shall not be less stringent than required by a subsequently promulgated effluent limitations guideline).

(18) When the permit becomes final and effective on or after March 9, 1982, and the permittee applies for the modification no later than January 24, 1985, if the permittee shows good cause in its request and that it qualifies for the modification, to conform to changes respecting the following regulations issued under that Settlement Agreement:

40 CFR 122.45(b)
40 CFR 122.45(c)
40 CFR 122.50

* * * * *

14. Section 122.63 is amended by adding a new paragraph (f) to read as follows:

**§ 122.63 Minor modifications of permits.**

* * * * *

(f) When the permit becomes final and effective on or after March 9, 1982, conform to changes respecting §§ 122.41(e), 122.41(l), 122.41(m)(4)(i)(B), 122.41(n)(3)(i) and 122.42(a) issued September 26, 1984.

**Appendix D—NPDES Permit Application Testing Requirements (§ 122.21)**

15. Appendix D of Part 122 is amended by revising the heading for Table III to read as follows:

*Table III: Other Toxic Pollutants (Metals and Cyanide) and Total Phenols*

## PART 124—PROCEDURES FOR DECISIONMAKING

### Subpart A—General Program Requirements

16. Section 124.13 is revised to read as follows:

**§ 124.13 Obligation to raise issues and provide information during the public comment period.**

All persons, including applicants, who believe any condition of a draft permit is inappropriate or that the Director's tentative decision to deny an application, terminate a permit, or prepare a draft permit is inappropriate, must raise all reasonably ascertainable issues and submit all reasonably available arguments supporting their position by the close of the public comment period (including any public hearing) under § 124.10. Any supporting materials which are submitted shall be included in full and may not be incorporated by reference, unless they are already part of the administrative record in the same proceeding, or consist of State or Federal statutes and regulations, EPA documents of general applicability, or other generally available reference materials. Commenters shall make supporting materials not already included in the administrative record available to EPA as directed by the Regional Administrator. (A comment period longer than 30 days may be necessary to give commenters a reasonable opportunity to comply with the requirements of this section. Additional time shall be granted under § 124.10 to the extent that a commenter who requests additional time demonstrates the need for such time.)

17. Section 124.14 is amended by redesignating paragraphs (a) through (d) as (b) through (e) and by adding a new paragraph (a) to read as follows:

**§ 124.14 Reopening of the public comment period.**

(a)(1) The Regional Administrator may order the public comment period reopened if the procedures of this paragraph could expedite the decisionmaking process. When the public comment period is reopened under this paragraph, all persons, including applicants, who believe any condition of a draft permit is inappropriate or that the Regional Administrator's tentative decision to deny an application, terminate a permit, or prepare a draft permit is inappropriate, must submit all reasonably available factual grounds supporting their position, including all supporting material, by a date, not less than sixty days after public notice under paragraph (a)(2) of this section, set by the Regional Administrator. Thereafter, any person may file a written response to the material filed by any other person, by a date, not less than twenty days after the date set for filing of the material, set by the Regional Administrator.

(2) Public notice of any comment period under this paragraph shall identify the issues to which the requirements of § 124.14(a) shall apply.

(3) On his own motion or on the request of any person, the Regional Administrator may direct that the requirements of paragraph (a)(1) of this section shall apply during the initial comment period where it reasonably appears that issuance of the permit will be contested and that applying the requirements of paragraph (a)(1) of this section will substantially expedite the decisionmaking process. The notice of the draft permit shall state whenever this has been done.

(4) A comment period of longer than 60 days will often be necessary in complicated proceedings to give commenters a reasonable opportunity to comply with the requirements of this section. Commenters may request longer comment periods and they shall be granted under § 124.10 to the extent they appear necessary.

* * * * *

### Subpart D—Specific Procedures Applicable to NPDES Permits

18. Section 124.56 is amended by adding a new paragraph (b)(1)(iv) to read as follows:

* * * * *

**§ 124.56 Fact sheets.**

(b) * * *

(1) * * *

(iv) Limitations set on a case-by-case basis under § 125.3 (c)(2) or (c)(3).

* * * * *

### Subpart E—Evidentiary Hearings for EPA-Issued NPDES Permits and EPA-Terminated RCRA Permits

19. Section 124.76 is revised to read as follows:

**§ 124.76 Obligation to submit evidence and raise issues before a final permit is issued.**

In any case where the Regional Administrator elected to apply the requirements of § 124.14(a), no evidence shall be submitted by any party to a

hearing under this Subpart that was not submitted to the administrative record required by § 124.18 as part of the preparation of and comment on a draft permit, unless good cause is shown for the failure to submit it. No issues shall be raised by any party that were not submitted to the administrative record required by § 124.18 as part of the preparation of and comment on a draft permit unless good cause is shown for the failure to submit them. Good cause includes the case where the party seeking to raise the new issues or introduce new information shows that it could not reasonably have ascertained the issues or made the information available within the time required by § 124.15; or that it could not have reasonably anticipated the relevance or materiality of the information sought to be introduced. Good cause exists for the introduction of data available on operation authorized under § 124.60(a)(2).

20. Section 124.78 is amended by revising paragraph (a)(1) to read as follows:

**§ 124.78 Ex parte communications.**

(a) * * *

(1) "Agency trial staff" means those Agency employees, whether temporary or permanent, who have been designated by the Agency under § 124.77 or § 124.116 as available to investigate, litigate, and present the evidence, arguments, and position of the Agency in the evidentiary hearing or nonadversary panel hearing. Any EPA employee, consultant, or contractor who is called as a witness by EPA trial staff, or who assisted in the formulation of the draft permit which is the subject of the hearing, shall be designated as a member of the Agency trial staff;

* * * * *

21. Section 124.85 is amended by adding a new paragraph (e) to read as follows:

**§ 124.85 Hearing procedure.**

* * * * *

(e) *Admission of Evidence on Environmental Impacts.* If a hearing is granted under this Subpart for a new source subject to NEPA, the Presiding Officer may admit evidence relevant to any environmental impacts of the permitted facility if the evidence would be relevant to the Agency's obligation under § 122.29(c)(3). If the source holds a final EPA-issued RCRA, PSD, or UIC permit, or an ocean dumping permit under the Marine Protection, Research, and Sanctuaries Act (MPRSA), no such evidence shall be admitted nor shall cross-examination be allowed relating to: (1) Effects on air quality, (2) effects attributable to underground injection or hazardous waste management practices, or (3) effects of ocean dumping subject to the MPRSA, which were considered or could have been considered in the PSD, RCRA, UIC, or MPRSA permit issuance proceedings. However, the presiding officer may admit without cross-examination or any supporting witness relevant portions of the record of PSD, RCRA, UIC, or MPRSA permit issuance proceedings.

## Subpart F—Non-Adversary Panel Procedures

22. Section 124.120 is amended by revising paragraph (a) as follows:

**§ 124.120 Panel hearing.**

(a) A Presiding Officer shall preside at each hearing held under this Subpart. An EPA panel shall also take part in the hearing. The panel shall consist of three or more EPA temporary or permanent employees having special expertise or responsibility in areas related to the hearing issue, none of whom shall have taken part in formulating the draft permit. If appropriate for the evaluation of new or different issues presented at the hearing, the panel membership, at the discretion of the Regional Administrator, may change or may include persons not employed by EPA.

* * * * *

23. Section 124.121 is amended by revising paragraphs (a)(1), (b) and (f) to read as follows:

**§ 124.121 Opportunity for cross-examination.**

(a) * * *

(1) The disputed issue(s) of material fact. This shall include an explanation of why the questions at issue are factual, the extent to which they are in dispute in light of the then existing record, and the extent to which they are material to the decision on the application; and

* * * * *

(b) After receipt of all motions for cross-examination under paragraph (a) of this section, the Presiding Officer, after consultation with the hearing panel, shall promptly issue an order either granting or denying each request. No cross-examination shall be allowed on questions of policy except to the extent required to disclose the factual basis for permit requirements, or on questions of law, or regarding matters (such as the validity of effluent limitations guidelines) that are not subject to challenge in permit issuance proceedings. Orders granting requests for cross-examination shall be served on all parties and shall specify:

* * * * *

(f) The provisions of §§ 124.85(d)(2) and 124.84(e) apply to proceedings under this Subpart.

## PART 125—CRITERIA AND STANDARDS FOR THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

24. Section 125.3 is amended by revising paragraph (c)(2), redesignating paragraphs (d) through (g) as (e) through (h) and adding a new paragraph (d) to read as follows:

**§ 125.3 Technology-based treatment requirements in permits.**

* * * * *

(c) * * *

(2) On a case-by-case basis under section 402(a)(1) of the Act, to the extent that EPA-promulgated effluent limitations are inapplicable. The permit writer shall apply the appropriate factors listed in § 125.3(d) and shall consider:

(i) The appropriate technology for the category or class of point sources of which the applicant is a member, based upon all available information; and

(ii) Any unique factors relating to the applicant.

* * * * *

(d) In setting case-by-case limitations pursuant to § 125.3(c), the permit writer must consider the following factors:

(1) For BPT requirements:

(i) The total cost of application of technology in relation to the effluent reduction benefits to be achieved from such application;

(ii) The age of equipment and facilities involved;

(iii) The process employed;

(iv) The engineering aspects of the application of various types of control techniques;

(v) Process changes; and

(vi) Non-water quality environmental impact (including energy requirements).

(2) For BCT requirements:

(i) The reasonableness of the relationship between the costs of attaining a reduction in effluent and the effluent reduction benefits derived;

(ii) The comparison of the cost and level of reduction of such pollutants from the discharge from publicly owned treatment works to the cost and level of reduction of such pollutants from a class or category of industrial sources;

(iii) The age of equipment and facilities involved;

(iv) The process employed;

(v) The engineering aspects of the application of various types of control techniques;

(vi) Process changes; and

(vii) Non-water quality environmental impact (including energy requirements).

(3) For BAT requirements:

(i) The age of equipment and facilities involved;

(ii) The process employed;

(iii) The engineering aspects of the application of various types of control techniques;

(iv) Process changes;

(v) The cost of achieving such effluent reduction; and

(vi) Non-water quality environmental impact (including energy requirements).

* * * * *

BILLING CODE 6560-50-M

# INSTRUCTIONS — FORM 2c
## Application for Permit to Discharge Wastewater
## EXISTING MANUFACTURING, COMMERCIAL, MINING, AND SILVICULTURAL OPERATIONS

**This form must be completed by all applicants who check "yes" to item II-C in Form 1.**

**Public Availability of Submitted Information.**

Your application will not be considered complete unless you answer every question on this form and on Form I. If an item does not apply to you, enter "NA" *(for not applicable)* to show that you considered the question.

You may not claim as confidential any information required by this form or Form I, whether the information is reported on the forms or in an attachment. This information will be made available to the public upon request.

Any information you submit to EPA which goes beyond that required by this form or Form I you may claim as confidential, but claims for information which is effluent data will be denied. If you do not assert a claim of confidentiality at the time of submitting the information, EPA may make the information public without further notice to you. Claims of confidentiality will be handled in accordance with EPA's business confidentiality regulations at 40 CFR Part 2.

**Definitions**

All significant terms used in these instructions and in the form are defined in the glossary found in the General Instructions which accompany Form 1.

**EPA ID Number**

Fill in your EPA Identification Number at the top of each page of Form 2c. You may copy this number directly from item I of Form I.

**Item I**

You may use the map you provided for item XI of Form I to determine the latitude and longitude of each of your outfalls and the name of the receiving water.

**Item II-A**

The line drawing should show generally the route taken by water in your facility from intake to discharge. Show all operations contributing wastewater, including process and production areas, sanitary flows, cooling water, and stormwater runoff. You may group similar operations into a single unit, labeled to correspond to the more detailed listing in item II-B. The water balance should show average flows. Show all significant losses of water to products, atmosphere, and discharge. You should use actual measurements whenever available; otherwise use your best estimate. An example of an acceptable line drawing appears in Figure 2c-1 to these instructions.

**Item II-B**

List all sources of wastewater to each outfall. Operations may be described in general terms *(for example, "dye-making reactor" or "distillation tower")*. You may estimate the flow contributed by each source if no data are available. For stormwater discharges you may estimate the average flow, but you must indicate the rainfall event upon which the estimate is based and the method of estimation. For each treatment unit, indicate its size, flow rate, and retention time, and describe the ultimate disposal of any solid or liquid wastes not discharged. Treatment units should be listed in order and you should select the proper code from Table 2c-1 to fill in column 3-b for each treatment unit. Insert "XX" into column 3-b if no code corresponds to a treatment unit you list. If you are applying for a permit for a privately owned treatment works, you must also identify all of your contributors in an attached listing.

**Item II-C**

A discharge is intermittent unless it occurs without interruption during the operating hours of the facility, except for infrequent shutdowns for maintenance, process changes, or other similar activities. A discharge is seasonal if it occurs only during certain parts of the year. Fill in every applicable column in this item for each source of intermittent or seasonal discharges. Base your answers on actual data whenever available; otherwise, provide your best estimate. Report the highest daily value for flow rate and total volume in the "Maximum Daily" columns *(columns 4-1-2 and 4-b-2)*. Report the average of all daily values measured during days when discharge occurred within the last year in the "Long Term Average" columns *(columns 4-a-I and 4-b-I)*.

**Item III-A**

All effluent guidelines promulgated by EPA appear in the Federal Register and are published annually in 40 CFR Subchapter N. A guideline applies to you if you have any operations contributing process wastewater in any subcategory covered by a BPT, BCT, or BAT guideline. If you are unsure whether you are covered by a promulgated effluent guideline, check with your EPA Regional office *(Table 1 in the Form 1 instructions)*. You must check "yes" if an applicable effluent guideline has been promulgated, even if the guideline limitations are being contested in court. If you believe that a promulgated effluent guideline has been remanded for reconsideration by a court and does not apply to your operations, you may check "no."

**Item III-B**

An effluent guideline is expressed in terms of production *(or other measure of operation)* if the limitation is expressed as mass of pollutant per operational parameter; for example, "pounds of BOD per cubic foot of logs from which bark is removed," or "pounds of TSS per megawatt hour of electrical energy consumed by smelting furnace". An example of a guideline not expressed in terms of a measure of operation is one which limits the concentration of pollutants.

**Item III-C**

This item must be completed only if you checked "yes" to item III-B. The production information requested here is necessary to apply effluent guidelines to your facility and you cannot claim it as confidential. Report quantities in the units of measurement used in the applicable effluent guideline. The production figures provided must be based on actual daily production and not on design capacity or on predictions of future operations. To obtain alternate limits under 40 CFR 122.45(b)(2)(ii), you must define your maximum production capability and demonstrate to the Director that your actual production is substantially below maximum production capability and that there is a reasonable potential for an increase above actual production during the duration of the permit.

**Item IV-A**

If you check "yes" to this question, complete all parts of the chart, or attach a copy of any previous submission you have made to EPA containing same information.

**Item IV-B**

You are not required to submit a description of future pollution control projects if you do not wish to or if none is planned.

**Item V-A, B, C, and D**

The items require you to collect and report data on the pollutants discharged for each of your outfalls. Each part of this item addresses a different set of pollutants and must be completed in accordance with the specific instructions for that part. The following general instructions apply to the entire item.

**General Instructions**

Part A requires you to report at least one analysis for each pollutant listed. Parts B and C require you to report analytical data in two ways. For some pollutants, you may be required to mark 'X' in the "Testing Required" column *(column 2-a, Part C)*, and test *(sample and analyze)* and report the levels of the pollutants in your discharge whether or not you expect them to be present in your discharge. For all others, you must mark 'X' in either the "Believe Present" column or the "Believe Absent" column *(columns 2-a or 2-b, Part B, and columns 2-b or 2-c, Part C)* based on your best estimate, and test for those which you believe to be present. *(See specific instructions on the form and below for Parts A through D.)* Base your determination that a pollutant is present in or absent from your discharge on your knowledge of your raw materials, maintenance chemicals, inter-

## FORM 2C — INSTRUCTIONS *(continued)*

ITEM V — A, B, C, and D *(continued)*

mediate and final products and byproducts, and any previous analyses known to you of your effluent or similar effluent. *(For example, if you manufacture pesticides, you should expect those pesticides to be present in contaminated stormwater runoff.)* If you would expect a pollutant to be present solely as a result of its presence in your intake water, you must mark "Believe Present" but you are not required to analyze for that pollutant. Instead, mark an 'X' in the "Intake" column.

**A. Reporting.** All levels must be reported as concentration and as total mass. You may report some or all of the required data by attaching separate sheets of paper instead of filling out pages V-1 to V-9 if the separate sheets contain all the required information in a format which is consistent with pages V-1 to V-9 in spacing and in identification of pollutants and columns. *(For example, the data system used in your GC/MS analysis may be able to print data in the proper format.)* Use the following abbreviations in the columns headed "Units" *(column 3, Part A, and column 4, Parts B and C).*

| Concentration | Mass |
|---|---|
| ppm ..... parts per million | lbs ..... pounds |
| mg/l .... milligrams per liter | ton ..... tons *(English tons)* |
| ppb ..... parts per billion | mg ..... milligrams |
| ug/l .... micrograms per liter | g ..... grams |
| | kg ..... kilograms |
| | T ..... tonnes *(metric tons)* |

All reporting of values for metals must be in terms of "total recoverable metal," unless:

(1) An applicable, promulgated effluent limitation or standard specifies the limitation for the metal in dissolved, valent, or total form; or

(2) All approved analytical methods for the metal inherently measure only its dissolved form (e.g., hexavalent chromium); or

(3) The permitting authority has determined that in establishing case-by-case limitations it is necessary to express the limitations on the metal in dissolved, valent, or total form to carry out the provisions of the CWA.

If you measure only one daily value, complete only the "Maximum Daily Values" columns and insert '1' into the "Number of Analyses" column *(columns 2-a and 2-d, Part A, and column 3-a, 3-d, Parts B and C).* The permitting authority may require you to conduct additional analyses to further characterize your discharges. For composite samples, the daily value is the total mass or average concentration found in a composite sample taken over the operating hours of the facility during a 24-hour period; for grab samples, the daily value is the arithmetic or flow-weighted total mass or average concentration found in a series of at least four grab samples taken over the operating hours of the facility during a 24-hour period.

If you measure more than one daily value for a pollutant and those values are representative of your wastestream, you must report them. You must describe your method of testing and data analysis. You also must determine the average of all values within the last year and report the concentration and mass under the "Long Term Average Values" columns *(column 2-c, Part A, and column 3-c, Parts B and C),* and the total number of daily values under the "Number of Analyses" columns *(column 2-d, Part A, and columns 3-d, Parts B and C).* Also, determine the average of all daily values taken during each calendar month, and report the highest average under the "Maximum 30-day Values" columns *(column 2-c, Part A, and column 3-b, Parts B and C).*

**B. Sampling:** The collection of the samples for the reported analyses should be supervised by a person experienced in performing sampling of industrial wastewater. You may contact your EPA or State permitting authority for detailed guidance on sampling techniques and for answers to specific questions. Any specific requirements contained in the applicable analytical methods should be followed for sample containers, sample preservation, holding times, the collection of duplicate samples, etc. The time when you sample should be representative of your normal operation, to the extent feasible, with all processes which contribute wastewater in normal operation, and with your treatment system operating properly with no system upsets. Samples should be collected from the center of the flow channel, where turbulence is at a maximum, at a site specified in your present permit, or at any site adequate for the collection of a representative sample.

For pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, and fecal coliform, grab samples must be used. For all other pollutants 24-hour composite samples must be used. However, a minimum of one grab sample may be taken for effluents from holding ponds or other impoundments with a retention period of greater than 24 hours. For stormwater discharges a minimum of one to four grab samples may be taken, depending on the duration of the discharge. One grab must be taken in the first hour *(or less)* of discharge, with one additional grab *(up to a minimum of four)* taken in each succeeding hour of discharge for discharges lasting four or more hours. The Director may waive composite sampling for any outfall for which you demonstrate that use of an automatic sampler is infeasible and that a minimum of four grab samples will be representative of your discharge.

Grab and composite samples are defined as follows:

Grab sample: An individual sample of at least 100 milliliters collected at a randomly-selected time over a period not exceeding 15 minutes.

Composite sample: A combination of at least 8 sample aliquots of at least 100 milliliters, collected at periodic intervals during the operating hours of a facility over a 24 hour period. The composite must be flow proportional; either the time interval between each aliquot or the volume of each aliquot must be proportional to either the stream flow at the time of sampling or the total stream flow since the collection of the previous aliquot. Aliquots may be collected manually or automatically. For GC/MS Volatile Organic Analysis (VOA), aliquots must be combined in the laboratory immediately before analysis. Four (4) *(rather than eight)* aliquots or grab samples should be collected for VOA. These four samples should be collected during actual hours of discharge over a 24 hour period and need not be flow proportioned. Only one analysis is required.

The Agency is currently reviewing sampling requirements in light of recent research on testing methods. Upon completion of its review, the Agency plans to propose changes to the sampling requirements.

Data from samples taken in the past may be used, provided that:

All data requirements are met;

Sampling was done no more than three years before submission; and

All data are representative of the present discharge.

Among the factors which would cause the data to be unrepresentative are significant changes in production level, changes in raw materials, processes, or final products, and changes in wastewater treatment. When the Agency promulgates new analytical methods in 40 CFR Part 136, EPA will provide information as to when you should use the new methods to generate data on your discharges. Of course, the Director may request additional information, including current quantitative data, if she or he determines it to be necessary to assess your discharges.

**C. Analysis:** You must use test methods promulgated in 40 CFR Part 136; however, if none has been promulgated for a particular pollutant, you may use any suitable method for measuring the level of the pollutant in your discharge provided that you submit a description of the method or a reference to a published method. Your description should include the sample holding time, preservation techniques, and the quality control measures which you used. If you have two or more substantially identical outfalls, you may request permission from your permitting authority to sample and analyse only one outfall and submit the results of the analysis

## FORM 2C — INSTRUCTIONS *(continued)*

**ITEM V — A, B, C, and D** *(continued)*

for other substantially identical outfalls. If your request is granted by the permitting authority, on a separate sheet attached to the application form, identify which outfall you did test, and describe why the outfalls which you did not test are substantially identical to the outfall which you did test.

**D. Reporting of Intake Data:** You are not required to report data under the "Intake" columns unless you wish to demonstate your eligibility for a "net" effluent limitation for one or more pollutants, that is, an effluent limitation adjusted by subtracting the average level of the pollutant(s) present in your intake water. NPDES regulations allow net limitations only in certain circumstances. To demonstrate your eligibility, under the "Intake" columns report the average of the results of analyses on your intake water *(if your water is treated before use, test the water after it is treated)*, and discuss the requirements for a net limitation with your permitting authority.

**Part V-A**

Part V-A must be completed by all applicants for all outfalls, including outfalls containing only noncontact cooling water or storm runoff. However, at your request, the Director may waive the requirement to test for one or more of these pollutants, upon a determination that available information is adequate to support issuance of the permit with less stringent reporting requirements for these pollutants. You also may request a waiver for one or more of these pollutants for your category or subcategory from the Director, Office of Water Enforcement and Permits. See discussion in General Instructions to item V for definitions of the columns in Part A. The "Long Term Average Values" column *(column 2-c)* and "Maximum 30-day Values" column *(column 2-b)* are not compulsory but should be filled out if data are available.

**Part V-B**

Part V-B must be completed by all applicants for all outfalls, including outfalls containing only noncontact cooling water or storm runoff. You must report quantitative data if the pollutant(s) in question is limited in an effluent limitations guideline either directly, or indirectly but expressly through limitation on an indicator *(e.g., use of TSS as an indicator to control the discharge of iron and aluminum)*. For other discharged pollutants you must provide quantitative data or explain their presence in your discharge. Upon request the Director, Office of Water Enforcement and Permits, may waive the requirement to test for pollutantsfor an industrial category or subcategory. Your request must be supported by data representative of the industrial category or subcategory in question. The data must demonstrate that individual testing for each applicant is unnecessary, because the facilities in the category or subcategory discharge substantially identical levels of the pollutant or discharge the pollutant uniformly at sufficiently low levels.The "Long Term Average Values" column *(column 3-c)* and "Maximum 30-day Values" column *(column 30b)* are not compulsory but should be filled out if data are available.

**Part V-C**

Table 2c-2 lists the 34 "primary" industry categories in the left-hand column. For each outfall, if any of your processes which contribute wastewater falls into one of those categories, you must mark 'X' in "Testing Required" column *(column 2-a)* and test for (1) all of the toxic metals, cyanide, and total phenols, and (2) the organic toxic pollutants contained in Table 2c-2 as applicable to your category, unless you qualify as a small business *(see below)*. The organic toxic pollutants are listed by GC/MS fractions on pages V-4 to V-9 in Part V-C. For example, the Organic Chemicals Industry has an asterisk in all four fractions; therefore, applicants in this category must test for all organic toxic pollutants in Part V-C. The inclusion of total phenols in Part V-C is not intended to classify total phenols as a toxic pollutant. If you are applying for a permit for a privately owned treatment works, determine your testing requirements on the basis of the industry categories of your contributors. When you determine which industry category you are in to find your testing requirements, you are not determining your category for any other purpose and you are not giving up your right to challenge your inclusion in that category *(for example, for deciding whether an effluent guideline is applicable)* before your permit is issued. For all other cases *(secondary industries, nonprocess wastewater outfalls, and non-required GC/MS fractions)*, you must mark "X" in either the "Believed Present" column *(column 2-b)* or the "Believed Absent" column *(column 2-c)* for each pollutant. For every pollutant you know or have reason to believe is present in your discharge in concentrations of 10 ppb or greater, you must report quantitative data. For acrolein, acrylonitrile, 2, 4 dinitrophenol, and 2-methyl-4, 6 dinitrophenol, where you expect these four pollutants to be discharged in concentrations of 100 ppb or greater, you must report quantitative data. For every pollutant expected to be discharged in concentrations less than the thresholds specified above, you must either submit quantitative data or briefly describe the reasons the pollutant is expected to be discharged. At your request the Director, Office of Water Enforcement and Permits, may waive the requirement to test for pollutants for an industrial category or subcategory. Your request must be supported by data representatives of the industrial category or subcategory in question. The data must demonstrate that individual testing for each applicant is unnecessary, because the facilities in question discharge substantially identical levels of the pollutant, or discharge the pollutant uniformly at sufficiently low levels. If you qualify as a small business *(see below)* you are exempt from testing for the organic toxic pollutants, listed on pages V-4 to V-9 in Part C. For pollutants in intake water, see discussion in General Instructions to this item. The "Long Term Average Values" column *(column 3-c)* and "Maximum 30-day Values" column *(column 30-b)* are not compulsory but should be filled out if data are available.You are required to mark "Testing Required" for dioxin if you use or manufacture one of the following compounds:

(a) 2,4,5-trichlorophenoxy acetic acid, (2,4,5-T);

(b) 2-(2,4,5-trichlorophenoxy) propanoic acid, (Silvex, 2,4,5-TP);

(c) 2-(2,4,5-trichlorophenoxy) ethyl 2,2-dichloropropionate, (Erbon);

(d) 0,0-dimethyl 0-(2,4,5-trichlorophenyl) phosphorothioate, (Ronnel);

(e) 2,4,5,-trichlorophnol, (TCP); or

(f) hexachlorophene, (HCP).

If you mark "Testing Required" or "Believed Present," you must perform a screening analysis for dioxins, using gas chromotography with an electron capture detector. A TCDD standard for quantitation is not required. Describe the results of this analysis in the space provided; for example, "no measurable baseline deflection at the retention time of TCDD" or "a measurable peak within the tolerances of the retention time of TCDD." The permitting authority may require you to perform a quantitative analysis if you report a positive result. The Effluent Guidelines Division of EPA has collected and analyzed samples from some plants for the pollutants listed in Part C in the course of its BAT guidelines development program. If your effluents are sampled and analyzed as part of this program in the last three years, you may use these data to answer Part C provided that the permitting authority approves, and provided that no process change or change in raw materials or operating practices has occurred since the samples were taken that would make the analyses unrepresentative of your current discharge.

**Small Business Exemption:** If you qualify as a "small business," you are exempt from the reporting requirements for the organic toxic pollutants, listed on pages V-4 to V-9 in Part C. There are two ways in which you can qualify as a "small business." If your facility is a coal mine, and if your probable total annual production is less than 100,000 tons per year, you may submit past production data or estimated future production *(such as a schedule of estimated total production under 30 CFR § 795.14(c))* instead of conducting analyses for the organic toxic pollutants. If your facil-

## FORM 2C — INSTRUCTIONS *(continued)*

**ITEM V — A, B, C, and D** *(continued)*

ity is not a coal mine, and if your gross total annual sales for the most recent three years average less than $100,000 per year *(in second quarter 1980 dollars)*, you may submit sales data for those years instead of conducting analyses for the organic toxic pollutants. The production or sales data must be for the facility which is the source of the discharge. The data should not be limited to production or sales for the process or processs which contribute to the discharge, unless those are the only processes at your facility. For sales data, in situations involving intracorporate transfer of goods and services, the transfer price per unit should approximate market prices for those goods and services as closely as possible. Sales figures for years after 1980 should be indexed to the second quarter of 1980 by using the gross national product price deflator *(second quarter of 1980* = 100). This index is available in *National Income and Product Accounts of the United States (Department of Commerce, Bureau of Economic Analysis)*.

**Part V-D**

List any pollutants in Table 2c-3 that you believe to be present and explain why you believe them to be present. No analysis is required, but if you have analytical data, you must report it.

**Note:** Under 40 CFR 117.12(a)(2), certain discharges of hazardous substances *(listed in Table 2c-4 of these instructions)* may be exempted from the requirements of section 311 of CWA, which establishes reporting requirements, civil penalties and liability for cleanup costs for spills of oil and hazardous substances. A discharge of a particular substance may be exempted if the origin, source, and amount of the discharged substances are identified in the NDPES permit application or in the permit, if the permit contains a requirement for treatment of the discharge, and if the treatment is in place. To apply for an exclusion of the discharge of any hazardous substance from the requirements of section 311, attach additional sheets of paper to your form, setting forth the following information:

1. The substance and the amount of each substance which may be discharged.
2. The origin and source of the discharge of the substance.
3. The treatment which is to be provided for the discharge by:
   a. An onsite treatment system separate from any treatment system treating your normal discharge;
   b. A treatment system designed to treat your normal discharge and which is additionally capable of treating the amount of the substance identified under paragraph 1 above; or
   c. Any combination of the above.

See 40 CFR §117.12(a)(2ind(C), published on August 29, 1979, in 44 FR 50766, or contact your Regional Office *(Table 1 on Form 1, Instructions)*, for further information on exclusions from section 311.

**Item VI**

This requirement applies to current use or manufacture of a toxic pollutant as an intermediate or final product or byproduct. The Director may waive or modify the requirement if you demonstrate that it would be unduly burdensome to identify each toxic pollutant and the Director has adequate information to issue your permit. You may not claim this information as confidential; however, you do not have to distinguish between use or production of the pollutants or list the amounts. Under NPDES regulations your permit will contain limits to control all pollutants you report in answer to this question, as well as all pollutants reported in Item V at levels exceeding the technology-based limits appropriate to your facility.

**Item VII**

Self explanatory. The permitting authority may ask you to provide additional details after your application is received.

**Item IX**

The Clean Water Act provides for severe penalties for submitting false information on this application form.

Section 309(c)(12) of the Clean Water Act provides that "Any person who knowingly makes any false statement, representation, or certification in any application, ... shall upon conviction, be punished by a fine of no more than $10,000 or by imprisonment for more than six months, or both."

40 CFR Part 122.22 requires the certification to be signed as follows:

(A) *For a corporation:* by a responsible corporate official. For purposes of this section, a responsible corporate official means (i) a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policyor decision-making functions for the corporation, or (ii) the manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding $25,000,000 *(in second-quarter 1980 dollars)*, if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

**Note:** EPA does not require specific assignments or delegation of authority to responsible corporate officers identified in §122.22(a)(1)(i). The Agency will presume that these responsible corporate officers have the requisite authority to sign permit applications unless the corporation has notified the director to the contrary. Corporate procedures governing authority to sign permit applications may provide for assignment or delegation to applicable corporate position under §122.22(a)(1)(ii) rather than to specific individuals.

(B) *For a partnership or sole proprietorship:* by a general partner or the proprietor, respectively; or

(C) *For a municipality, State, Federal, or other public agency:* by either a principal executive officer or ranking elected official. For purposes of this section, a principal executive officer of a Federal Agency includes (i) the chief executive officer of the Agency, or (ii) a senior executive officer having responsibility for the overall operations of a principal geographic unit of the Agency *(e.g., Regional Administrators of EPA)*. Applications for Group II stormwater dischargers may be signed by a duly authorized representative *(as defined in 40 CFR 122.22(b))* of the individuals identified above.

## CODES FOR TREATMENT UNITS

### PHYSICAL TREATMENT PROCESSES

1–A . . . . . .Ammonia Stripping
1–B. . . . . .Dialysis
1–C. . . . . .Diatomaceous Earth Filtration
1–D . . . . . .Distillation
1–E. . . . . .Electrodialysis
1–F. . . . . .Evaporation
1–G . . . . . .Flocculation
1–H . . . . . .Flotation
1–I . . . . . .Foam Fractionation
1–J. . . . . .Freezing
1–K . . . . . .Gas–Phase Separation
1–L. . . . . .Grinding *(Comminutors)*
1–M . . . . . .Grit Removal
1–N . . . . . .Microstraining
1–O . . . . . .Mixing
1–P. . . . . .Moving Bed Filters
1–Q . . . . . .Multimedia Filtration
1–R . . . . . .Rapid Sand Filtration
1–S. . . . . .Reverse Osmosis *(Hyperfiltration)*
1–T. . . . . .Screening
1–U . . . . . .Sedimentation *(Settling)*
1–V . . . . . .Slow Sand Filtration
1–W . . . . . .Solvent Extraction
1–X . . . . . .Sorption

### CHEMICAL TREATMENT PROCESSES

2–A . . . . . .Carbon Adsorption
2–B. . . . . .Chemical Oxidation
2–C. . . . . .Chemical Precipitation
2–D . . . . . .Coagulation
2–E. . . . . .Dechlorination
2–F. . . . . .Disinfection *(Chlorine)*
2–G . . . . . .Disinfection *(Ozone)*
2–H . . . . . .Disinfection *(Other)*
2–I . . . . . .Electrochemical Treatment
2–J. . . . . .Ion Exchange
2–K . . . . . .Neutralization
2–L. . . . . .Reduction

### BIOLOGICAL TREATMENT PROCESSES

3–A . . . . . .Activated Sludge
3–B. . . . . .Aerated Lagoons
3–C. . . . . .Anaerobic Treatment
3–D . . . . . .Nitrification–Denitrification
3–E. . . . . .Pre–Aeration
3–F. . . . . .Spray Irrigation/Land Application
3–G . . . . . .Stabilization Ponds
3–H . . . . . .Trickling Filtration

### OTHER PROCESSES

4–A . . . . . .Discharge to Surface Water
4–B. . . . . .Ocean Discharge Through Outfall
4–C. . . . . .Reuse/Recycle of Treated Effluent
4–D . . . . . .Underground Injection

### SLUDGE TREATMENT AND DISPOSAL PROCESSES

5–A . . . . . .Aerobic Digestion
5–B. . . . . .Anaerobic Digestion
5–C. . . . . .Belt Filtration
5–D . . . . . .Centrifugation
5–E. . . . . .Chemical Conditioning
5–F. . . . . .Chlorine Treatment
5–G . . . . . .Composting
5–H . . . . . .Drying Beds
5–I . . . . . .Elutriation
5–J. . . . . .Flotation Thickening
5–K . . . . . .Freezing
5–L. . . . . .Gravity Thickening
5–M . . . . . .Heat Drying
5–N . . . . . .Heat Treatment
5–O . . . . . .Incineration
5–P. . . . . .Land Application
5–Q . . . . . .Landfill
5–R . . . . . .Pressure Filtration
5–S. . . . . .Pyrolysis
5–T. . . . . .Sludge Lagoons
5–U . . . . . .Vacuum Filtration
5–V . . . . . .Vibration
5–W . . . . . .Wet Oxidation

TABLE 2C-1

## TESTING REQUIREMENTS FOR ORGANIC TOXIC POLLUTANTS INDUSTRY CATEGORY*

| INDUSTRY CATEGORY | GC/MS FRACTION[1] | | | |
|---|---|---|---|---|
| | Volatile | Acid | Base/Neutral | Pesticide |
| Adhesives and sealants | X | X | X | – |
| Aluminum forming | X | X | X | – |
| Auto and other laundries | X | X | X | X |
| Battery manufacturing | X | – | X | – |
| Coal mining | X | X | X | X |
| Coil coating | X | X | X | – |
| Copper forming | X | X | X | – |
| Electric and electronic compounds | X | X | X | X |
| Electroplating | X | X | X | – |
| Explosives manufacturing | – | X | X | – |
| Foundries | X | X | X | – |
| Gum and wood chemicals | X | X | X | X |
| Inorganic chemicals manufacturing | X | X | X | – |
| Iron and steel manufacturing | X | X | X | – |
| Leather tanning and finishing | X | X | X | X |
| Mechanical products manufacturing | X | X | X | – |
| Nonferrous metals manufacturing | X | X | X | X |
| Ore mining | X | X | X | X |
| Organic chemicals manufacturing | X | X | X | X |
| Paint and ink formulation | X | X | X | X |
| Pesticides | X | X | X | X |
| Petroleum refining | X | X | X | X |
| Pharmaceutical preparations | X | X | X | – |
| Photographic equipment and supplies | X | X | X | X |
| Plastic and synthetic materials manufacturing | X | X | X | X |
| Plastic processing | X | – | – | – |
| Porcelain enameling | X | – | X | X |
| Printing and publishing | X | X | X | X |
| Pulp and paperboard mills | X | X | X | X |
| Rubber processing | X | X | X | – |
| Soap and detergent manufacturing | X | X | X | – |
| Steam electric power plants | X | X | X | – |
| Textile mills | X | X | X | X |
| Timber products processing | X | X | X | X |

*See note at conclusion of 40 CFR Part 122, Appendix D (1983) for explanation of effect of suspensions on testing requirements for primary industry categories.

[1]The pollutants in each fraction are listed in Item V—C.

X = Testing required.

— = Testing not required.

TABLE 2C-2

## TOXIC POLLUTANTS AND HAZARDOUS SUBSTANCES REQUIRED TO BE IDENTIFIED BY APPLICANTS IF EXPECTED TO BE PRESENT

TOXIC POLLUTANT

Asbestos

HAZARDOUS SUBSTANCES

Acetaldehyde
Allyl alcohol
Allyl chloride
Amyl acetate
Aniline
Benzonitrile
Benzyl chloride
Butyl acetate
Butylamine
Captan
Carbaryl
Carbofuran
Carbon disulfide
Chlorpyrifos
Coumaphos
Cresol
Crotonaldehyde
Cyclohexane
2,4-D (2,4-Dichlorophenoxyacetic acid)
Diazinon
Dicamba
Dichlobenil
Dichlone
2,2-Dichloropropionic acid

HAZARDOUS SUBSTANCES

Dichlorvos
Diethyl amine
Dimethyl amine
Dintrobenzene
Diquat
Disulfoton
Diuron
Epichlorohydrin
Ethion
Ethylene diamine
Ethylene dibromide
Formaldehyde
Furfural
Guthion
Isoprene
Isopropanolamine
Kelthane
Kepone
Malathion
Mercaptodimethur
Methoxychlor
Methyl mercaptan
Methyl methacrylate
Methyl parathion
Mevinphos
Mexacarbate
Monoethyl amine
Monomethyl amine

HAZARDOUS SUBSTANCES

Naled
Napthenic acid
Nitrotoluene
Parathion
Phenolsulfonate
Phosgene
Propargite
Propylene oxide
Pyrethrins
Quinoline
Resorcinol
Strontium
Strychnine
Styrene
2,4,5-T (2,4,5-Trichlorophenoxyacetic acid)
TDE (Tetrachlorodiphenyl ethane)
2,4,5-TP [2-(2,4,5-Trichlorophenoxy) propanoic acid]
Trichlorofon
Triethanolamine
Triethylamine
Trimethylamine
Uranium
Vanadium
Vinyl acetate
Xylene
Xylenol
Zirconium

TABLE 2C-3

## HAZARDOUS SUBSTANCES

1. Acetaldehyde
2. Acetic acid
3. Acetic anhydride
4. Acetone cyanohydrin
5. Acetyl bromide
6. Acetyl chloride
7. Acrolein
8. Acrylonitrile
9. Adipic acid
10. Aldrin
11. Allyl alcohol
12. Allyl chloride
13. Aluminum sulfate
14. Ammonia
15. Ammonium acetate
16. Ammonium benzoate
17. Ammonium bicarbonate
18. Ammonium bichromate
19. Ammonium bifluoride
20. Ammonium bisulfite
21. Ammonium carbamate
22. Ammonium carbonate
23. Ammonium chloride
24. Ammonium chromate
25. Ammonium citrate
26. Ammonium fluoroborate
27. Ammonium fluoride
28. Ammonium hydroxide
29. Ammonium oxalate
30. Ammonium silicofluoride
31. Ammonium sulfamate
32. Ammonium sulfide
33. Ammonium sulfite
34. Ammonium tartrate
35. Ammonium thiocyanate
36. Ammonium thiosulfate
37. Amyl acetate
38. Aniline
39. Antimony pentachloride
40. Antimony potassium tartrate
41. Antimony tribromide
42. Antimony trichloride
43. Antimony trifluoride
44. Antimony trioxide
45. Arsenic disulfide
46. Arsenic pentoxide
47. Arsenic trichloride
48. Arsenic trioxide
49. Arsenic trisulfide
50. Barium cyanide
51. Benzene
52. Benzoic acid
53. Benzonitrile
54. Benzoyl chloride
55. Benzyl chloride
56. Beryllium chloride
57. Beryllium fluoride
58. Beryllium nitrate
59. Butylacetate
60. n-Butylphthalate
61. Butylamine
62. Butyric acid
63. Cadmium acetate
64. Cadmium bromide
65. Cadmium chloride
66. Calcium arsenate
67. Calcium arsenite
68. Calcium carbide
69. Calcium chromate
70. Calcium cyanide
71. Calcium dodecylbenzenesulfonate
72. Calcium hypochlorite
73. Captan
74. Carbaryl
75. Carbofuran
76. Carbon disulfide
77. Carbon tetrachloride
78. Chlordane
79. Chlorine
80. Chlorobenzene
81. Chloroform
82. Chloropyrifos
83. Chlorosulfonic acid
84. Chromic acetate
85. Chromic acid
86. Chromic sulfate
87. Chromous chloride
88. Cobaltous bromide
89. Cobaltous formate
90. Cobaltous sulfamate
91. Coumaphos
92. Cresol
93. Crotonaldehyde
94. Cupric acetate
95. Cupric acetoarsenite
96. Cupric chloride
97. Cupric nitrate
98. Cupric oxalate
99. Cupric sulfate
100. Cupric sulfate ammoniated
101. Cupric tartrate
102. Cyanogen chloride
103. Cyclohexane
104. 2,4-D acid (2,4-Dichlorophenoxyacetic acid)
105. 2,4-D esters (2,4-Dichlorophenoxyacetic acid esters)
106. DDT
107. Diazinon
108. Dicamba
109. Dichlobenil
110. Dichlone
111. Dichlorobenzene
112. Dichloropropane
113. Dichloropropene
114. Dichloropropene-dichloproropane mix
115. 2,2-Dichloropropionic acid
116. Dichlorvos
117. Dieldrin
118. Diethylamine
119. Dimethylamine
120. Dinitrobenzene
121. Dinitrophenol
122. Dinitrotoluene
123. Diquat
124. Disulfoton
125. Diuron
126. Dodecylbenzesulfonic acid
127. Endosulfan
128. Endrin
129. Epichlorohydrin
130. Ethion
131. Ethylbenzene
132. Ethylenediamine
133. Ethylene dibromide
134. Ethylene dichloride
135. Ethylene diaminetetracetic acid (EDTA)
136. Ferric ammonium citrate
137. Ferric ammonium oxalate
138. Ferric chloride
139. Ferric fluoride
140. Ferric nitrate
141. Ferric sulfate
142. Ferrous ammonium sulfate
143. Ferrous chloride
144. Ferrous sulfate
145. Formaldehyde
146. Formic acid
147. Fumaric acid
148. Furfural
149. Guthion
150. Heptachlor
151. Hexachlorocyclopentadiene
152. Hydrochloric acid
153. Hydrofluoric acid
154. Hydrogen cyanide
155. Hydrogen sulfite
156. Isoprene
157. Isopropanolamine dodecylbenzenesulfonate
158. Kelthane
159. Kepone
160. Lead acetate
161. Lead arsenate
162. Lead chloride
163. Lead fluoborate
164. Lead flourite
165. Lead iodide
166. Lead nitrate
167. Lead stearate
168. Lead sulfate
169. Lead sulfide
170. Lead thiocyanate
171. Lindane
172. Lithium chromate
173. Malathion
174. Maleic acid
175. Maleic anhydride
176. Mercaptodimethur
177. Mercuric cyanide
178. Mercuric nitrate
179. Mercuric sulfate
180. Mercuric thiocyanate
181. Mercurous nitrate
182. Methoxychlor
183. Methyl mercaptan
184. Methyl methacrylate
185. Methyl parathion
186. Mevinphos
187. Mexacarbate
188. Monoethylamine
189. Monomethylamine
190. Naled
191. Napthalene
192. Napthenic acid
193. Nickel ammonium sulfate
194. Nickel chloride
195. Nickel hydroxide
196. Nickel nitrate
197. Nickel sulfate
198. Nitric acid
199. Nitrobenzene
200. Nitrogen dioxide
201. Nitrophenol
202. Nitrotoluene
203. Paraformaldehyde

TABLE 2C-4

**HAZARDOUS SUBSTANCES *(continued)***

204. Parathion
205. Pentachlorophenol
206. Phenol
207. Phosgene
208. Phosphoric acid
209. Phosphorus
210. Phosphorus oxychloride
211. Phosphorus pentasulfide
212. Phosphorus trichloride
213. Polychlorinated biphenyls (PCB)
214. Potassium arsenate
215. Potassium arsenite
216. Potassium bichromate
217. Potassium chromate
218. Potassium cyanide
219. Potassium hydroxide
220. Potassium permanganate
221. Propargite
222. Propionic acid
223. Propionic anhydride
224. Propylene oxide
225. Pyrethrins
226. Quinoline
227. Resorcinol
228. Selenium oxide
229. Silver nitrate
230. Sodium
231. Sodium arsenate
232. Sodium arsenite
233. Sodium bichromate
234. Sodium bifluoride
235. Sodium bisulfite
236. Sodium chromate
237. Sodium cyanide
238. Sodium dodecylbenzenesulfonate
239. Sodium fluoride
240. Sodium hydrosulfide
241. Sodium hydroxide
242. Sodium hypochlorite
243. Sodium methylate
244. Sodium nitrite
245. Sodum phosphate (dibasic)
246. Sodium phosphate (tribasic)
247. Sodium selenite
248. Strontium chromate
249. Strychnine
250. Styrene
251. Sulfuric acid
252. Sulfur monochloride
253. 2,4,5-T acid (2,4,5-Trichlorophenoxyacetic acid)
254. 2,4,5-T amines (2,4,5-Trichlorophenoxy acetic acid amines)
255. 2,4,5-T esters (2,4,5-Trichlorophenoxy acetic acid esters)
256. 2,4,5-T salts (2,4,5-Trichlorophenoxy acetic acid salts)
257. 2,4,5-TP acid (2,4,5-Trichlorophenoxy propanoic acid)
258. 2,4,5-TP acid esters (2,4,5-Trichlorophenoxy propanoic acid esters)
259. TDE (Tetrachlorodiphenyl ethane)
260. Tetraethyl lead
261. Tetraethyl pyrophosphate
262. Thallium sulfate
263. Toluene
264. Toxaphene
265. Trichlorofon
266. Trichloroethylene
267. Trichlorophenol
268. Triethanolamine dodecylbenzenesulfonate
269. Triethylamine
270. Trimethylamine
271. Uranyl acetate
272. Uranyl nitrate
273. Vanadium pentoxide
274. Vanadyl sulfate
275. Vinyl acetate
276. Vinylidene chloride
277. Xylene
278. Xylenol
279. Zinc acetate
280. Zinc ammonium chloride
281. Zinc borate
282. Zinc bromide
283. Zinc carbonate
284. Zinc chloride
285. Zinc cyanide
286. Zinc fluoride
287. Zinc formate
288. Zinc hydrosulfonate
289. Zinc nitrate
290. Zinc phenolsulfonate
291. Zinc phosphide
292. Zinc silicofluoride
293. Zinc sulfate
294. Zirconium nitrate
295. Zirconium potassium flouride
296. Zirconium sulfate
297. Zirconium tetrachloride

**TABLE 2C-4 *(continued)***

LINE DRAWING

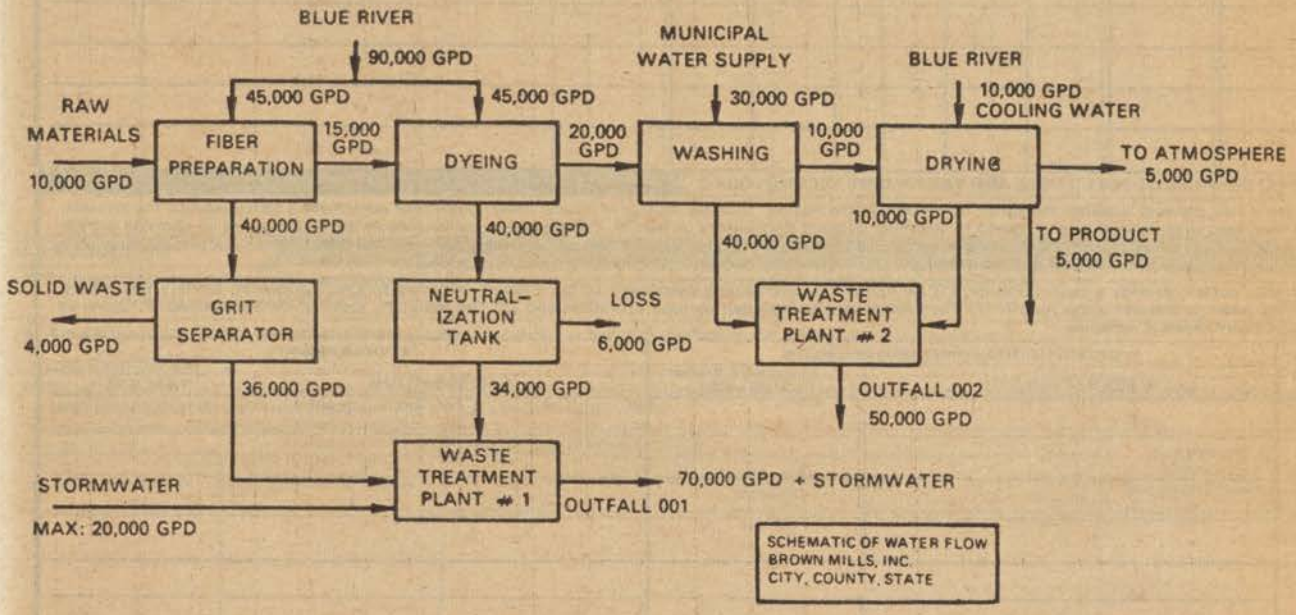



FIGURE 2C-1

EPA I.D. NUMBER *(copy from Item 1 of Form 1)*

Please print or type in the unshaded areas only.

FORM 2C NPDES EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
APPLICATION FOR PERMIT TO DISCHARGE WASTEWATER
EXISTING MANUFACTURING, COMMERCIAL, MINING AND SILVICULTURAL OPERATIONS
*Consolidated Permits Program*

## I. OUTFALL LOCATION

For each outfall, list the latitude and longitude of its location to the nearest 15 seconds and the name of the receiving water.

| A. OUTFALL NUMBER *(list)* | B. LATITUDE | | | C. LONGITUDE | | | D. RECEIVING WATER *(name)* |
|---|---|---|---|---|---|---|---|
| | 1. DEG. | 2. MIN. | 3. SEC. | 1. DEG. | 2. MIN. | 3. SEC. | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## II. FLOWS, SOURCES OF POLLUTION, AND TREATMENT TECHNOLOGIES

A. Attach a line drawing showing the water flow through the facility. Indicate sources of intake water, operations contributing wastewater to the effluent, and treatment units labeled to correspond to the more detailed descriptions in Item B. Construct a water balance on the line drawing by showing average flows between intakes, operations, treatment units, and outfalls. If a water balance cannot be determined *(e.g., for certain mining activities)*, provide a pictorial description of the nature and amount of any sources of water and any collection or treatment measures.

B. For each outfall, provide a description of: (1) All operations contributing wastewater to the effluent, including process wastewater, sanitary wastewater, cooling water, and storm water runoff; (2) The average flow contributed by each operation; and (3) The treatment received by the wastewater. Continue on additional sheets if necessary.

| 1. OUT-FALL NO *(list)* | 2. OPERATION(S) CONTRIBUTING FLOW | | 3. TREATMENT | |
|---|---|---|---|---|
| | a. OPERATION *(list)* | b. AVERAGE FLOW *(include units)* | a. DESCRIPTION | b. LIST CODES FROM TABLE 2C-1 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

OFFICIAL USE ONLY *(effluent guidelines sub-categories)*

EPA Form 3510-2C (Rev. 4-84)



CONTINUE ON REVERSE

CONTINUED FROM THE FRONT

C. Except for storm runoff, leaks, or spills, are any of the discharges described in Items II-A or B intermittent or seasonal?

☐ YES *(complete the following table)* ☐ NO *(go to Section III)*

| 1. OUTFALL NUMBER *(list)* | 2. OPERATION(s) CONTRIBUTING FLOW *(list)* | 3. FREQUENCY | | 4. FLOW | | | | |
|---|---|---|---|---|---|---|---|---|
| | | a. DAYS PER WEEK *(specify average)* | b. MONTHS PER YEAR *(specify average)* | a. FLOW RATE *(in mgd)* | | b. TOTAL VOLUME *(specify with units)* | | c. DURATION *(in days)* |
| | | | | 1. LONG TERM AVERAGE | 2. MAXIMUM DAILY | 1. LONG TERM AVERAGE | 2. MAXIMUM DAILY | |
| | | | | | | | | |

## III. PRODUCTION

A. Does an effluent guideline limitation promulgated by EPA under Section 304 of the Clean Water Act apply to your facility?

☐ YES *(complete Item III-B)* ☐ NO *(to to Section IV)*

B. Are the limitations in the applicable effluent guideline expressed in terms of production *(or other measure of operation)*?

☐ YES *(complete Item III-C)* ☐ NO *(go to Section IV)*

C. If you answered "yes" to Item III-B, list the quantity which represents an actual measurement of your level of production, expressed in the terms and units used in the applicable effluent guideline, and indicate the affected outfalls.

| 1. AVERAGE DAILY PRODUCTION | | | 2. AFFECTED OUTFALLS *(list outfall numbers)* |
|---|---|---|---|
| a. QUANTITY PER DAY | b. UNITS OF MEASURE | c. OPERATION, PRODUCT, MATERIAL, ETC. *(specify)* | |
| | | | |

## IV. IMPROVEMENTS

A. Are you now required by any Federal, State or local authority to meet any implementation schedule for the construction, upgrading or operation of wastewater treatment equipment or practices or any other environmental programs which may affect the discharges described in this application? This includes, but is not limited to, permit conditions, administrative or enforcement orders, enforcement compliance schedule letters, stipulations, court orders, and grant or loan conditions.

☐ YES *(complete the following table)* ☐ NO *(go to Item IV-B)*

| 1. IDENTIFICATION OF CONDITION, AGREEMENT, ETC. | 2. AFFECTED OUTFALLS | | 3. BRIEF DESCRIPTION OF PROJECT | 4. FINAL COMPLIANCE DATE | |
|---|---|---|---|---|---|
| | a. NO. | b. SOURCE OF DISCHARGE | | a. REQUIRED | b. PROJECTED |
| | | | | | |

B. OPTIONAL: You may attach additional sheets describing any additional water pollution control programs *(or other environmental projects which may affect your discharges)* you now have underway or which you plan. Indicate whether each program is now underway or planned, and indicate your actual or planned schedules for construction. ☐ MARK "X" IF DESCRIPTION OF ADDITIONAL CONTROL PROGRAMS IS ATTACHED

EPA I.D. NUMBER *(copy from Item 1 of Form 1)*

CONTINUED FROM PAGE 2

## V. INTAKE AND EFFLUENT CHARACTERISTICS

A, B, & C: See instructions before proceeding – Complete one set of tables for each outfall – Annotate the outfall number in the space provided. NOTE: Tables V-A, V-B, and V-C are included on separate sheets numbered V-1 through V-9.

D. Use the space below to list any of the pollutants listed in Table 2c-3 of the instructions, which you know or have reason to believe is discharged or may be discharged from any outfall. For every pollutant you list, briefly describe the reasons you believe it to be present and report any analytical data in your possession.

| 1. POLLUTANT | 2. SOURCE | 1. POLLUTANT | 2. SOURCE |
|---|---|---|---|
| | | | |

## VI. POTENTIAL DISCHARGES NOT COVERED BY ANALYSIS

Is any pollutant listed in Item V-C a substance or a component of a substance which you currently use or manufacture as an intermediate or final product or byproduct?

☐ YES *(list all such pollutants below)* ☐ NO *(go to Item VI-B)*

CONTINUED FROM THE FRONT

## VII. BIOLOGICAL TOXICITY TESTING DATA

Do you have any knowledge or reason to believe that any biological test for acute or chronic toxicity has been made on any of your discharges or on a receiving water in relation to your discharge within the last 3 years?

☐ YES *(identify the test(s) and describe their purposes below)* ☐ NO *(go to Section VIII)*

## VIII CONTRACT ANALYSIS INFORMATION

Were any of the analyses reported in Item V performed by a contract laboratory or consulting firm?

☐ YES *(list the name, address, and telephone number of, and pollutants analyzed by, each such laboratory or firm below)* ☐ NO *(go to Section IX)*

| A. NAME | B. ADDRESS | C. TELEPHONE *(area code & no.)* | D. POLLUTANTS ANALYZED *(list)* |
|---|---|---|---|
| | | | |

## IX. CERTIFICATION

*I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.*

| A. NAME & OFFICIAL TITLE *(type or print)* | B. PHONE NO. *(area code & no.)* |
|---|---|
| C. SIGNATURE | D. DATE SIGNED |

PLEASE PRINT OR TYPE IN THE UNSHADED AREAS ONLY. You may report some or all of this information on separate sheets *(use the same format)* instead of completing these pages. SEE INSTRUCTIONS.

EPA I.D. NUMBER *(copy from Item 1 of Form 1)*

OUTFALL NO.

**V. INTAKE AND EFFLUENT CHARACTERISTICS** *(continued from page 3 of Form 2-C)*

PART A - You must provide the results of at least one analysis for every pollutant in this table. Complete one table for each outfall. See instructions for additional details.

| 1. POLLUTANT | 2. EFFLUENT | | | | | | | 3. UNITS (specify if blank) | | 4. INTAKE (optional) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE (if available) | | c. LONG TERM AVRG. VALUE (if available) | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO. OF ANALYSES |
| | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| a. Biochemical Oxygen Demand *(BOD)* | | | | | | | | | | | | |
| b. Chemical Oxygen Demand *(COD)* | | | | | | | | | | | | |
| c. Total Organic Carbon *(TOC)* | | | | | | | | | | | | |
| d. Total Suspended Solids *(TSS)* | | | | | | | | | | | | |
| e. Ammonia *(as N)* | | | | | | | | | | | | |
| f. Flow | VALUE | | VALUE | | VALUE | | | | | VALUE | | |
| g. Temperature *(winter)* | VALUE | | VALUE | | VALUE | | | °C | | VALUE | | |
| h. Temperature *(summer)* | VALUE | | VALUE | | VALUE | | | °C | | VALUE | | |
| i. pH | MINIMUM | MAXIMUM | MINIMUM | MAXIMUM | | | | STANDARD UNITS | | | | |

PART B - Mark "X" in column 2-a for each pollutant you know or have reason to believe is present. Mark "X" in column 2-b for each pollutant you believe to be absent. If you mark column 2a for any pollutant which is limited either directly, or indirectly but expressly, in an effluent limitations guideline, you must provide the results of at least one analysis for that pollutant. For other pollutants for which you mark column 2a, you must provide quantitative data or an explanation of their presence in your discharge. Complete one table for each outfall. See the instructions for additional details and requirements.

| 1. POLLUTANT AND CAS NO. *(if available)* | 2. MARK 'X' | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE (optional) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. BELIEVED PRESENT | b. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE (if available) | | c. LONG TERM AVRG. VALUE (if available) | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO. OF ANALYSES |
| | | | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| a. Bromide (24959-67-9) | | | | | | | | | | | | | | |
| b. Chlorine, Total Residual | | | | | | | | | | | | | | |
| c. Color | | | | | | | | | | | | | | |
| d. Fecal Coliform | | | | | | | | | | | | | | |
| e. Fluoride (16984-48-8) | | | | | | | | | | | | | | |
| f. Nitrate–Nitrite *(as N)* | | | | | | | | | | | | | | |

ITEM V-B CONTINUED FROM FRONT

| 1. POLLUTANT AND CAS NO. (if available) | 2. MARK 'X' | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE (optional) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. BELIEVED PRESENT | b. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE (1) CONCENTRATION | a. MAXIMUM DAILY VALUE (2) MASS | b. MAXIMUM 30 DAY VALUE (if available) (1) CONCENTRATION | b. MAXIMUM 30 DAY VALUE (if available) (2) MASS | c. LONG TERM AVRG. VALUE (if available) (1) CONCENTRATION | c. LONG TERM AVRG. VALUE (if available) (2) MASS | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE (1) CONCENTRATION | a. LONG TERM AVERAGE VALUE (2) MASS | b. NO. OF ANALYSES |
| g. Nitrogen, Total Organic (as N) | | | | | | | | | | | | | | |
| h. Oil and Grease | | | | | | | | | | | | | | |
| i. Phosphorus (as P), Total (7723-14-0) | | | | | | | | | | | | | | |
| j. Radioactivity | | | | | | | | | | | | | | |
| (1) Alpha, Total | | | | | | | | | | | | | | |
| (2) Beta, Total | | | | | | | | | | | | | | |
| (3) Radium, Total | | | | | | | | | | | | | | |
| (4) Radium 226, Total | | | | | | | | | | | | | | |
| k. Sulfate (as $SO_4$) (14808-79-8) | | | | | | | | | | | | | | |
| l. Sulfide (as S) | | | | | | | | | | | | | | |
| m. Sulfite (as $SO_3$) (14265-45-3) | | | | | | | | | | | | | | |
| n. Surfactants | | | | | | | | | | | | | | |
| o. Aluminum, Total (7429-90-5) | | | | | | | | | | | | | | |
| p. Barium, Total (7440-39-3) | | | | | | | | | | | | | | |
| q. Boron, Total (7440-42-8) | | | | | | | | | | | | | | |
| r. Cobalt, Total (7440-48-4) | | | | | | | | | | | | | | |
| s. Iron, Total (7439-89-6) | | | | | | | | | | | | | | |
| t. Magnesium, Total (7439-95-4) | | | | | | | | | | | | | | |
| u. Molybdenum, Total (7439-98-7) | | | | | | | | | | | | | | |
| v. Manganese, Total (7439-96-5) | | | | | | | | | | | | | | |
| w. Tin, Total (7440-31-5) | | | | | | | | | | | | | | |
| x. Titanium, Total (7440-32-6) | | | | | | | | | | | | | | |



CONTINUE ON PAGE V - 3

| EPA I.D. NUMBER *(copy from Item 1 of Form 1)* | OUTFALL NUMBER |
|---|---|
| | |

CONTINUED FROM PAGE 3 OF FORM 2-C

PART C - If you are a primary industry and this outfall contains process wastewater, refer to Table 2c-2 in the instructions to determine which of the GC/MS fractions you must test for. Mark "X" in column 2-a for all such GC/MS fractions that apply to your industry and for ALL toxic metals, cyanides, and total phenols. If you are not required to mark column 2-a *(secondary industries, nonprocess wastewater outfalls, and nonrequired GC/MS fractions)*, mark "X" in column 2-b for each pollutant you know or have reason to believe is present. Mark "X" in column 2-c for each pollutant you believe is absent. If you mark column 2a for any pollutant, you must provide the results of at least one analysis for that pollutant. If you mark column 2b for any pollutant, you must provide the results of at least one analysis for that pollutant if you know or have reason to believe it will be discharged in concentrations of 10 ppb or greater. If you mark column 2b for acrolein, acrylonitrile, 2,4 dinitrophenol, or 2-methyl-4, 6 dinitrophenol, you must provide the results of at least one analysis for each of these pollutants which you know or have reason to believe that you discharge in concentrations of 100 ppb or greater. Otherwise, for pollutants for which you mark column 2b, you must either submit at least one analysis or briefly describe the reasons the pollutant is expected to be discharged. Note that there are 7 pages to this part; please review each carefully. Complete one table *(all 7 pages)* for each outfall. See instructions for additional details and requirements.

| 1. POLLUTANT AND CAS NUMBER *(if available)* | 2. MARK 'X' | | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE *(optional)* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. TESTING REQUIRED | b. BELIEVED PRESENT | c. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE *(if available)* | | c. LONG TERM AVRG. VALUE *(if available)* | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO. OF ANALYSES |
| | | | | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| **METALS, CYANIDE, AND TOTAL PHENOLS** | | | | | | | | | | | | | | | |
| 1M. Antimony, Total (7440-36-0) | | | | | | | | | | | | | | | |
| 2M. Arsenic, Total (7440-38-2) | | | | | | | | | | | | | | | |
| 3M. Beryllium, Total, 7440-41-7) | | | | | | | | | | | | | | | |
| 4M. Cadmium, Total (7440-43-9) | | | | | | | | | | | | | | | |
| 5M. Chromium, Total (7440-47-3) | | | | | | | | | | | | | | | |
| 6M. Copper, Total (7440-50-8) | | | | | | | | | | | | | | | |
| 7M. Lead, Total (7439-92-1) | | | | | | | | | | | | | | | |
| 8M. Mercury, Total (7439-97-6) | | | | | | | | | | | | | | | |
| 9M. Nickel, Total (7440-02-0) | | | | | | | | | | | | | | | |
| 10M. Selenium, Total (7782-49-2) | | | | | | | | | | | | | | | |
| 11M. Silver, Total (7440-22-4) | | | | | | | | | | | | | | | |
| 12M. Thallium, Total (7440-28-0) | | | | | | | | | | | | | | | |
| 13M. Zinc, Total (7440-66-6) | | | | | | | | | | | | | | | |
| 14M. Cyanide, Total (57-12-5) | | | | | | | | | | | | | | | |
| 15M. Phenols, Total | | | | | | | | | | | | | | | |
| **DIOXIN** | | | | | | | | | | | | | | | |
| 2,3,7,8-Tetrachlorodibenzo-P-Dioxin (1764-01-6) | | | | DESCRIBE RESULTS | | | | | | | | | | | |

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| 1. POLLUTANT AND CAS NUMBER (if available) | 2. MARK 'X' | | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE (optional) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. TESTING REQUIRED | b. BELIEVED PRESENT | c. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE (if available) | | c. LONG TERM AVRG. VALUE (if available) | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO. OF ANALYSES |
| | | | | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| GC/MS FRACTION – VOLATILE COMPOUNDS | | | | | | | | | | | | | | | |
| 1V. Acrolein (107-02-8) | | | | | | | | | | | | | | | |
| 2V. Acrylonitrile (107-13-1) | | | | | | | | | | | | | | | |
| 3V. Benzene (71-43-2) | | | | | | | | | | | | | | | |
| 4V. Bis (Chloromethyl) Ether (542-88-1) | | | | | | | | | | | | | | | |
| 5V. Bromoform (75-25-2) | | | | | | | | | | | | | | | |
| 6V. Carbon Tetrachloride (56-23-5) | | | | | | | | | | | | | | | |
| 7V. Chlorobenzene (108-90-7) | | | | | | | | | | | | | | | |
| 8V. Chlorodibromomethane (124-48-1) | | | | | | | | | | | | | | | |
| 9V. Chloroethane (75-00-3) | | | | | | | | | | | | | | | |
| 10V. 2-Chloroethylvinyl Ether (110-75-8) | | | | | | | | | | | | | | | |
| 11V. Chloroform (67-66-3) | | | | | | | | | | | | | | | |
| 12V. Dichlorobromomethane (75-27-4) | | | | | | | | | | | | | | | |
| 13V. Dichlorodifluoromethane (75-71-8) | | | | | | | | | | | | | | | |
| 14V. 1,1-Dichloroethane (75-34-3) | | | | | | | | | | | | | | | |
| 15V. 1,2-Dichloroethane (107-06-2) | | | | | | | | | | | | | | | |
| 16V. 1,1-Dichloroethylene (75-35-4) | | | | | | | | | | | | | | | |
| 17V. 1,2-Dichloropropane (78-87-5) | | | | | | | | | | | | | | | |
| 18V. 1,3-Dichloropropylene (542-75-6) | | | | | | | | | | | | | | | |
| 19V. Ethylbenzene (100-41-4) | | | | | | | | | | | | | | | |
| 20V. Methyl Bromide (74-83-9) | | | | | | | | | | | | | | | |
| 21V. Methyl Chloride (74-87-3) | | | | | | | | | | | | | | | |



CONTINUE ON PAGE V-5

| EPA I.D. NUMBER *(copy from Item 1 of Form 1)* | OUTFALL NUMBER |
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CONTINUED FROM PAGE V-4

| 1. POLLUTANT AND CAS NUMBER *(if available)* | 2. MARK 'X' | | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE *(optional)* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. TESTING REQUIRED | b. BELIEVED PRESENT | c. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE *(if available)* | | c. LONG TERM AVRG. VALUE *(if available)* | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO. OF ANALYSES |
| | | | | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| **GC/MS FRACTION – VOLATILE COMPOUNDS** *(continued)* | | | | | | | | | | | | | | | |
| 22V. Methylene Chloride (75-09-2) | | | | | | | | | | | | | | | |
| 23V. 1,1,2,2-Tetrachloroethane (79-34-5) | | | | | | | | | | | | | | | |
| 24V. Tetrachloroethylene (127-18-4) | | | | | | | | | | | | | | | |
| 25V. Toluene (108-88-3) | | | | | | | | | | | | | | | |
| 26V. 1,2-Trans-Dichloroethylene (156-60-5) | | | | | | | | | | | | | | | |
| 27V. 1,1,1-Trichloroethane (71-55-6) | | | | | | | | | | | | | | | |
| 28V. 1,1,2-Trichloroethane (79-00-5) | | | | | | | | | | | | | | | |
| 29V. Trichloroethylene (79-01-6) | | | | | | | | | | | | | | | |
| 30V. Trichlorofluoromethane (75-69-4) | | | | | | | | | | | | | | | |
| 31V. Vinyl Chloride (75-01-4) | | | | | | | | | | | | | | | |
| **GC/MS FRACTION – ACID COMPOUNDS** | | | | | | | | | | | | | | | |
| 1A. 2-Chlorophenol (95-57-8) | | | | | | | | | | | | | | | |
| 2A. 2,4-Dichlorophenol (120-83-2) | | | | | | | | | | | | | | | |
| 3A. 2,4-Dimethylphenol (105-67-9) | | | | | | | | | | | | | | | |
| 4A. 4,6-Dinitro-O-Cresol (534-52-1) | | | | | | | | | | | | | | | |
| 5A. 2,4-Dinitrophenol (51-28-5) | | | | | | | | | | | | | | | |
| 6A. 2-Nitrophenol (88-75-5) | | | | | | | | | | | | | | | |
| 7A. 4-Nitrophenol (100-02-7) | | | | | | | | | | | | | | | |
| 8A. P-Chloro-M-Cresol (59-50-7) | | | | | | | | | | | | | | | |
| 9A. Pentachlorophenol (87-86-5) | | | | | | | | | | | | | | | |
| 10A. Phenol (108-95-2) | | | | | | | | | | | | | | | |
| 11A. 2,4,6-Trichlorophenol (88-06-2) | | | | | | | | | | | | | | | |



CONTINUE ON REVERSE

| 1. POLLUTANT AND CAS NUMBER (if available) | 2. MARK 'X' | | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE (optional) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. TESTING REQUIRED | b. BELIEVED PRESENT | c. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE (if available) | | c. LONG TERM AVRG. VALUE (if available) | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO. OF ANALYSES |
| | | | | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| GC/MS FRACTION – BASE/NEUTRAL COMPOUNDS | | | | | | | | | | | | | | | |
| 1B. Acenaphthene (83-32-9) | | | | | | | | | | | | | | | |
| 2B. Acenaphtylene (208-96-8) | | | | | | | | | | | | | | | |
| 3B. Anthracene (120-12-7) | | | | | | | | | | | | | | | |
| 4B. Benzidine (92-87-5) | | | | | | | | | | | | | | | |
| 5B. Benzo *(a)* Anthracene (56-55-3) | | | | | | | | | | | | | | | |
| 6B. Benzo *(a)* Pyrene (50-32-8) | | | | | | | | | | | | | | | |
| 7B. 3,4-Benzo-fluoranthene (205-99-2) | | | | | | | | | | | | | | | |
| 8B. Benzo *(ghi)* Perylene (191-24-2) | | | | | | | | | | | | | | | |
| 9B. Benzo *(k)* Fluoranthene (207-08-9) | | | | | | | | | | | | | | | |
| 10B. Bis *(2-Chloro-ethoxy)* Methane (111-91-1) | | | | | | | | | | | | | | | |
| 11B. Bis *(2-Chloro-ethyl)* Ether (111-44-4) | | | | | | | | | | | | | | | |
| 12B. Bis *(2-Chloroiso-propyl)* Ether (102-60-1) | | | | | | | | | | | | | | | |
| 13B. Bis *(2-Ethyl-hexyl)* Phthalate (117-81-7) | | | | | | | | | | | | | | | |
| 14B. 4-Bromo-phenyl Phenyl Ether (101-55-3) | | | | | | | | | | | | | | | |
| 15B. Butyl Benzyl Phthalate (85-68-7) | | | | | | | | | | | | | | | |
| 16B. 2-Chloro-naphthalene (91-58-7) | | | | | | | | | | | | | | | |
| 17B. 4-Chloro-phenyl Phenyl Ether (7005-72-3) | | | | | | | | | | | | | | | |
| 18B. Chrysene (218-01-9) | | | | | | | | | | | | | | | |
| 19B. Dibenzo *(a,h)* Anthracene (53-70-3) | | | | | | | | | | | | | | | |
| 20B. 1,2-Dichloro-benzene (95-50-1) | | | | | | | | | | | | | | | |
| 21B. 1,3-Dichloro-benzene (541-73-1) | | | | | | | | | | | | | | | |

EPA I.D. NUMBER *(copy from Item 1 of Form 1)* | OUTFALL NUMBER

CONTINUED FROM PAGE V-6

| 1. POLLUTANT AND CAS NUMBER *(if available)* | 2. MARK 'X' | | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE *(optional)* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. TESTING REQUIRED | b. BELIEVED PRESENT | c. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE (1) CONCENTRATION | a. MAXIMUM DAILY VALUE (2) MASS | b. MAXIMUM 30 DAY VALUE *(if available)* (1) CONCENTRATION | b. MAXIMUM 30 DAY VALUE *(if available)* (2) MASS | c. LONG TERM AVRG. VALUE *(if available)* (1) CONCENTRATION | c. LONG TERM AVRG. VALUE *(if available)* (2) MASS | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE (1) CONCENTRATION | a. LONG TERM AVERAGE VALUE (2) MASS | b. NO. OF ANALYSES |
| **GC/MS FRACTION – BASE/NEUTRAL COMPOUNDS** *(continued)* | | | | | | | | | | | | | | | |
| 22B. 1,4-Dichlorobenzene (106-46-7) | | | | | | | | | | | | | | | |
| 23B. 3,3'-Dichlorobenzidine (91-94-1) | | | | | | | | | | | | | | | |
| 24B. Diethyl Phthalate (84-66-2) | | | | | | | | | | | | | | | |
| 25B. Dimethyl Phthalate (131-11-3) | | | | | | | | | | | | | | | |
| 26B. Di-N-Butyl Phthalate (84-74-2) | | | | | | | | | | | | | | | |
| 27B. 2,4-Dinitrotoluene (121-14-2) | | | | | | | | | | | | | | | |
| 28B. 2,6-Dinitrotoluene (606-20-2) | | | | | | | | | | | | | | | |
| 29B. Di-N-Octyl Phthalate (117-84-0) | | | | | | | | | | | | | | | |
| 30B. 1,2-Diphenylhydrazine *(as Azobenzene)* (122-66-7) | | | | | | | | | | | | | | | |
| 31B. Fluoranthene (206-44-0) | | | | | | | | | | | | | | | |
| 32B. Fluorene (86-73-7) | | | | | | | | | | | | | | | |
| 33B. Hexachlorobenzene (118-74-1) | | | | | | | | | | | | | | | |
| 34B. Hexachlorobutadiene (87-68-3) | | | | | | | | | | | | | | | |
| 35B. Hexachlorocyclopentadiene (77-47-4) | | | | | | | | | | | | | | | |
| 36B. Hexachloroethane (67-72-1) | | | | | | | | | | | | | | | |
| 37B. Indeno *(1,2,3-cd)* Pyrene (193-39-5) | | | | | | | | | | | | | | | |
| 38B. Isophorone (78-59-1) | | | | | | | | | | | | | | | |
| 39B. Naphthalene (91-20-3) | | | | | | | | | | | | | | | |
| 40B. Nitrobenzene (98-95-3) | | | | | | | | | | | | | | | |
| 41B. N-Nitrosodimethylamine (62-75-9) | | | | | | | | | | | | | | | |
| 42B. N-Nitrosodi-N-Propylamine (621-64-7) | | | | | | | | | | | | | | | |



CONTINUE ON REVERSE

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| 1. POLLUTANT AND CAS NUMBER (if available) | 2. MARK 'X' | | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE (optional) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. TESTING REQUIRED | b. BELIEVED PRESENT | c. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE (if available) | | c. LONG TERM AVRG. VALUE (if available) | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO OF ANALYSES |
| | | | | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| **GC/MS FRACTION – BASE/NEUTRAL COMPOUNDS** *(continued)* | | | | | | | | | | | | | | | |
| 43B. N-Nitrosodiphenylamine (86-30-6) | | | | | | | | | | | | | | | |
| 44B. Phenanthrene (85-01-8) | | | | | | | | | | | | | | | |
| 45B. Pyrene (129-00-0) | | | | | | | | | | | | | | | |
| 46B. 1,2,4 - Trichlorobenzene (120-82-1) | | | | | | | | | | | | | | | |
| **GC/MS FRACTION – PESTICIDES** | | | | | | | | | | | | | | | |
| 1P. Aldrin (309-00-2) | | | | | | | | | | | | | | | |
| 2P. α-BHC (319-84-6) | | | | | | | | | | | | | | | |
| 3P. β-BHC (319-85-7) | | | | | | | | | | | | | | | |
| 4P. γ-BHC (58-89-9) | | | | | | | | | | | | | | | |
| 5P. δ-BHC (319-86-8) | | | | | | | | | | | | | | | |
| 6P. Chlordane (57-74-9) | | | | | | | | | | | | | | | |
| 7P. 4,4'-DDT (50-29-3) | | | | | | | | | | | | | | | |
| 8P. 4,4'-DDE (72-55-9) | | | | | | | | | | | | | | | |
| 9P. 4,4'-DDD (72-54-8) | | | | | | | | | | | | | | | |
| 10P. Dieldrin (60-57-1) | | | | | | | | | | | | | | | |
| 11P. α Endosulfan (115-29-7) | | | | | | | | | | | | | | | |
| 12P. β Endosulfan (115-29-7) | | | | | | | | | | | | | | | |
| 13P. Endosulfan Sulfate (1031-07-8) | | | | | | | | | | | | | | | |
| 14P. Endrin (72-20-8) | | | | | | | | | | | | | | | |
| 15P. Endrin Aldehyde (7421-93-4) | | | | | | | | | | | | | | | |
| 16P. Heptachlor (76-44-8) | | | | | | | | | | | | | | | |

| EPA I.D. NUMBER *(copy from Item 1 of Form 1)* | OUTFALL NUMBER |
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CONTINUED FROM PAGE V-8

| 1. POLLUTANT AND CAS NUMBER *(if available)* | 2. MARK 'X' | | | 3. EFFLUENT | | | | | | | 4. UNITS | | 5. INTAKE *(optional)* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | a. TESTING REQUIRED | b. BELIEVED PRESENT | c. BELIEVED ABSENT | a. MAXIMUM DAILY VALUE | | b. MAXIMUM 30 DAY VALUE *(if available)* | | c. LONG TERM AVRG. VALUE *(if available)* | | d. NO. OF ANALYSES | a. CONCENTRATION | b. MASS | a. LONG TERM AVERAGE VALUE | | b. NO. OF ANALYSES |
| | | | | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | (1) CONCENTRATION | (2) MASS | | | | (1) CONCENTRATION | (2) MASS | |
| **GC/MS FRACTION – PESTICIDES** *(continued)* | | | | | | | | | | | | | | | |
| 17P. Heptachlor Epoxide (1024-57-3) | | | | | | | | | | | | | | | |
| 18P. PCB-1242 (53469-21-9) | | | | | | | | | | | | | | | |
| 19P. PCB-1254 (11097-69-1) | | | | | | | | | | | | | | | |
| 20P. PCB-1221 (11104-28-2) | | | | | | | | | | | | | | | |
| 21P. PCB-1232 (11141-16-5) | | | | | | | | | | | | | | | |
| 22P. PCB-1248 (12672-29-6) | | | | | | | | | | | | | | | |
| 23P. PCB-1260 (11096-82-5) | | | | | | | | | | | | | | | |
| 24P. PCB-1016 (12674-11-2) | | | | | | | | | | | | | | | |
| 25P. Toxaphene (8001-35-2) | | | | | | | | | | | | | | | |



**EPA Form 3510-2C (Rev. 4-84)**

[FR Doc. 84-25227 Filed 9-25-84; 8:45 am]

BILLING CODE 6560-50-C

federal register

Wednesday
September 26, 1984

Part V

# Department of Transportation

## Federal Aviation Administration

14 CFR Part 25

Implementation of SAFER Propulsion System Recommendations; Advanced Notice of Proposed Rulemaking

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 25**

**[Docket No. 24251; Notice No. 84-17]**

## Implementation of SAFER Propulsion System Recommendations

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Advance notice of proposed rulemaking (ANPRM).

**SUMMARY:** This notice announces the FAA's preliminary intention to amend the airworthiness standards for transport category airplanes by adding a standard requiring fuel system protection during post-crash ground fires, and by requiring design features which would assure shutoff of engine fuel when post-crash ground fires occur. This proposal is the result of information from public hearings on aircraft fire safety and recommendations by the Special Aviation Fire and Explosion Reduction (SAFER) Advisory Committee. The objective of this rulemaking activity is to develop airworthiness standards which would provide protection against fuel tank explosions following a post-crash ground fire and which would assure engine fuel supply shutoff to reduce the fire hazard from spilled fuel. The purpose of this advance notice is to gain public participation in identifying and selecting a regulatory course of action by inviting interested persons to submit specific comments and arguments regarding this proposal.

**DATES:** Comments must be received on or before January 25, 1985.

**ADDRESS:** Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC-204), Docket No. 24251, 800 Independence Avenue SW., Washington, D.C. 20591, or delivered in duplicate to: Room 916, 800 Independence Avenue SW., Washington, D.C. Comments must be marked: Docket No. 24251. Comments may be inspected in Room 916 on weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. In addition, the FAA is maintaining an information docket of comments in the Office of the Regional Counsel (ANM-7), Federal Aviation Administration, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. Comments in the information docket may be inspected in the Office of the Regional Counsel weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Mr. James Walker, Policy and Procedures Branch (ANM-111), Regulations and Policy Office, Aircraft Certification Division, FAA Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168; telephone (206) 431-2116.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

This ANPRM is being issued under the FAA's policy for early public participation in rulemaking proceedings. An ANRPM is issued when it is found that reasonable outside inquiry is needed to identify and select a tentative or alternative course of action, or where it would be helpful to invite public participation in identifying and selecting a course of action.

Interested persons are invited to participate in these preliminary rulemaking procedures by submitting written data, views, or arguments. Commenters should identify the regulatory docket or notice number and submit comments in duplicate to the Rules Docket address above. All comments received on or before the closing date for comments will be considered by the Administrator before taking further rulemaking action. Comments are invited relating to the environmental, energy, or economic impact that might result from adopting these proposals. The proposals contained in this notice may be changed in light of comments received. All comments submitted will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket. If it is determined to be in the public interest to proceed with further rulemaking after considering the available data and comments received in response to this notice, a Notice or Proposed Rulemaking will be issued. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 24251." The postcard will be dated, time stamped, and returned to the commenter.

### Availability of ANPRM

Any person may obtain a copy of this ANPRM by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-430, 800 Independence Avenue SW., Washington, D.C. 20591, or by calling (202) 426-8058. Communications must identify the notice number of this ANPRM. Persons interested in being placed on a mailing list for future ANPRMs or NPRMs should also request a copy of Advisory Circular No. 11-2, Notice of Proposed Rulemaking Distribution System, which describes the application procedures.

### Background

As a result of information from public hearings on aircraft fire safety, the FAA established the Special Aviation Fire and Explosion Reduction (SAFER) Advisory Committee in June 1978, to "examine the factors affecting the ability of the aircraft cabin occupant to survive in the post-crash environment and the range of solutions available." The Committee consisted of 24 representatives of a wide range of aviation and general public interests. The technical support groups included approximately 150 of the world's top experts in fire research, accident investigation, materials development, and related fields. The Committee focused primarily on the problems of fuel spillage and cabin fire protection and looked into related aspects of post-crash survival.

The Committee reviewed worldwide transport aircraft accidents that have occurred since 1964 involving post-crash fuel tank explosions and identified 15 that were considered impact-survivable. The fuel tanks were initially undamaged in four of these accidents; two involved ground fires which propagated through the wing tank vent system into the fuel tanks and ignited the fuel vapors resulting in explosions; and two involved failure to stop fuel flow through a ruptured engine feedline downstream of the shutoff valve, which increased the ground fire intensity and externally heated the fuel tanks, causing explosions. The Committee concluded that the tank explosions could have been prevented or substantially delayed in these four accidents by design changes that have subsequently been developed and are included in this proposal. The remaining 11 tank explosion accidents involved major structural damage and large quantities of fuel spillage. The Committee concluded there was a low probability that any design change would have prevented or reduced the explosions that occurred in these accidents. Fuel tank explosions have a more severe effect on safe evacuation than post-

crash fires alone since the explosions tend to intensify the local fire which, in turn, impedes or prevents safe evacuation.

The Committee considered that vent flame arrestors or surge tank explosion suppression systems used in some current airplanes to protect against lightning-induced ignition at fuel vent outlets might also be able to delay propagation of ground fires and the resulting explosions in undamaged fuel systems by providing additional time for passenger evacuation. The Committee also considered a design practice in use on some current airplanes which provides closure of the fuel tank-to-engine shutoff valve with the engine fuel control shut off during the normal engine shutdown process. It was concluded that this could also greatly increase the probability of engine fuel supply shutoff in post-crash fires.

Vent flame arrestors and surge tank explosion suppression systems are used in some aircraft to protect against flame propagation due to lightning-induced ignition at fuel vent outlets on the undersurface of the wing near the wing tips in compliance with § 25.954 of the Federal Aviation Regulations (FAR), adopted August 11, 1967. Both of these systems are envisioned by the Committee as being capable of providing compliance with the requirements contained in proposed § 25.975(a)(7) and thereby minimize the possibility of flame propagation from ground fires. The effectiveness of these systems in a ground fire environment, however, has not been fully developed.

A flame arrestor consists of a stainless steel web of quenching cells or channels and is installed in the vent tube near the outlet at the undersurface of the wing. When a combustion wave enters a relatively cold quenching channel, heat from the flame front flows into the channel wall at a rate exceeding the rate of heat generation so that the temperature decreases and the combustion reaction ceases. However, if the total heat capacity of the arrestor is designed to accommodate the brief duration of combustion caused by a lightning strike and the arrestor is subjected to a sustained ground fire, the temperature of the arrestor will increase rapidly to a value where the arrestor will fail and the flames will penetrate the arrestor and propagate into the fuel tanks. Therefore, an arrestor designed for lightning-induced ignition may not provide protection against propagation of ground fires. To comply with proposed § 25.975(a)(7), it would be necessary to design an arrestor to prevent flame penetration and propagation through the vent system for a period of time equal to the time required for an external fire to heat the fuel and vapors in the wing tank to its ignition temperature or to heat the undersurface skin of the wing tank to ignite the vapors, whichever is greater. This period of time would be longer than the time it takes for a ground fire to propagate through an unprotected vent system.

One airplane manufacturer has conducted some flame holding tests on flame arrestors with 0.03 and 0.05 inch cell sizes at various hexane/air vapor outflow velocities. For the 0.03 inch cell size, tank ignition did not occur after 6.5–9.0 minutes of downstream flame exposure, depending upon the outflow velocity. Ignition occured for the 0.05 inch cell size at all outflow velocities tested with the minimum time for tank ignition occurring after 2.0 minutes of flame exposure. These test data indicate that flame propagation through the fuel vent and fuel tank explosions can be delayed by the use of vent flame arrestors which have been developed for that purpose.

An explosion suppression system includes a flame radiation sensor in the vent outlet tube to detect an oncoming flame front and to activate a one-shot fire extinguishment discharge system in a surge tank for automatic suppression of the combustion process when it reaches the tank. This system can provide fuel tank vent explosion protection during ground fires similar to a properly designed flame arrestor if provision is made for a multiple-shot extinguishment capability. This would require continued availability of electrical power to enable sensing of repeated flame fronts induced by an external fire and triggering of timely extinguishment discharges. In addition, the system must be capable of effective operation at elevated temperatures due to an external fire.

In one incident of a survivable crash, the tank-to-engine fuel shutoff valve was not closed by pulling the fire shutoff handle which allowed fuel to escape through a ruptured engine feedline and expand the ground fire. A design change following the accident was made in the fuel shutoff system to provide a redundant fuel tank shutoff valve actuation method under emergency conditions. Some airplanes currently incorporate the additional capability to close the fuel tank shutoff valve when the fuel shutoff lever on the throttle quadrant is moved to the cutoff position. This design practice or similar designs can easily be employed in all transport airplanes and is encompassed within this proposal.

On the basis of the considerations discussed above, the Committee made the following recommendations to the FAA (Reference SAFER Final Report, Vol. 1, No. FAA–ASF–80–4):

1. Amend Part 25 of the FAR to require fuel tank vent protection during ground fires by adding a new § 25.975(a)(7) to read: "Each vent to atmosphere must be designed to minimize the possiblity of external ground fires being propagated through the vent line to the tank vapor space, providing that the tank and vent structure remain intact."

2. Amend Part 25 of the FAR to require design practices that maximize the probability of engine fuel supply shutoff in potential fire situations.

The FAA generally concurs with the Committee's recommendations. The rule changes preliminarily proposed in this notice, in response to the Committee's recommendations, would require protection, in the case of survivable crashes, against propagation of post-crash ground fires through the intact fuel tank vent system into the fuel tanks, thereby preventing fuel tank explosions caused by this ignition source. They would also provide increased assurance of fuel tank shutoff valve actuation following an accident, thereby preventing release of fuel through a ruptured engine feedline from starting, expanding, or intensifying a ground fire. These measures would reduce the post-crash fire and explosion hazards and increase occupant survivability. The proposals are considered technically feasible and cost-effective, although further development and subsantiation will be necessary to verify the effectiveness of flame arrestor or explosion suppression system technology.

**Economic Evaluation**

The FAA expects that the most cost effective method of meeting the proposed new ground fire protection requirement will be an improved vent flame arrestor now used to comply with existing lightning protection requirements. Procurement and maintenance costs and the installed weight of this system are likely to be relatively low compared to an explosion suppression system. Costs are expected to be minor to incorporate designs for complying with the proposal to improve the probability of engine fuel supply shutoff in potential fire situations. Questions of an economic nature relating to these proposals are included for comment. If it is determined that

further rulemaking is appropriate, an NPRM and full regulatory evaluation will be issued containing an analysis of the costs and benefits of the proposed rules.

**Request for Information**

Persons responding to this notice are invited to specifically address the following questions and supply any other information considered pertinent to the FAA's decision in further rulemaking on this subject. Additionally, comments should address the proposed rule changes.

1. What safety benefits would be derived from the proposed rules?
2. What would the environmental impact be?
3. How would the proposed rules impact energy resources?
4. What alternative solutions would be equally effective?
5. Can modifications to existing equipment and fuel systems used for fuel system lightning protection be made to apply to the new regulation and what would be the estimated cost savings over a new system?
6. Should a flame arrestor test procedure and performance level be required? If so, what is a reasonable and representative requirement?
7. Should a flame suppression system test procedure and performance level be required? If so, what is a reasonable and representative requirement?
8. What would be the estimated cost for flame arrestor components and their installation?
9. What is the estimated life cycle cost for the flame arrestor system? Include costs for components, installation and maintenance, and the expected weight penalty.
10. What would be the estimated cost for purge tank flame suppression system components and their installation?
11. What is the estimated life cycle cost for a purge tank flame suppression system? Include component costs, installation and maintenance, and the expected weight penalty.
12. What would be the estimated cost for the dual shutoff feature and installation for the fuel tank shutoff valve requirement?
13. What is the estimated life cycle cost for the dual shutoff feature for the fuel tank shutoff valve requirement and its weight penalty?
14. How soon will production hardware be available for installation?
15. Should the proposed rule also apply to newly manufactured models of previously type certificated airplanes?
16. Should consideration be given to retrofitting transport airplanes in service?

**List of Subjects in 14 CFR Part 25**

Air transportation, Aircraft, Aviation safety.

**The Proposed Amendment**

Accordingly, the Federal Aviation Administration proposes to amend Part 25 of the Federal Aviation Regulations (14 CFR Part 25) as follows:

## PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES

1. By amending § 25.975 by adding a new paragraph (a)(7) to read as follows:

**§25.975 Fuel tank vents and carburetor vapor vents.**

(a) * * *

(7) Each fuel system must be designed to minimize the possibility of external ground fires being propagated through the vent system and any other openings to fuel tank vapor spaces, providing the tank and vent system components and structure remain intact.

2. By amending § 25.1189 by adding a new paragraph (i) to read as follows:

**§ 25.1189 Shutoff means.**

* * * * *

(i) The engine and auxiliary power unit (APU) fuel supply and fuel crossfeed systems shall be designed to provide a positive or otherwise redundant means of isolating the tank fuel to prevent fuel spillage or discharge during post-crash groun fire condition.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.45)

**Note:** This ANPRM seeks information from interested persons, including manufacturers and users of transport category airplanes and components, the general public, both foreign and domestic, and foreign airworthiness authorities in developing a proposed new airworthiness standard. Preliminary evaluation indicates that this document is not significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) since information is being requested, and no economic or regulatory impact is imposed on any person by this action. A full regulatory evaluation will be prepared if further rulemaking is warranted based on the comments received as a result of this notice.

Issued in Seattle, Washington on September 4, 1984.

**Wayne J. Barlow,**

*Acting Director, Northwest Mountain Region.*

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