

of exposure (MOE) for the overall U.S. population (all seasons) and the following subpopulations: all infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), females (13–19 years), females (13–50 years), males (13–19 years), males (>20 years), and seniors (>55 years). In this refined Tier 2 analysis, all evaluated population subgroups had an exposure equal to 0% of the aRfD with a corresponding MOE of >1 million at the 95<sup>th</sup> percentile.

**Foliar application use (pome fruit).** Tomen has conducted an acute dietary exposure Tier 1 analysis with Dietary Exposure Evaluation Model (DEEM) using proposed tolerance of 1 ppm, 100% crop treated and no adjustment of processing factor for the overall U.S. populations and the following subpopulations: all infants, nursing infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), and females (13–50 years). The results of Tier 1 analysis from foliar use of pome fruit indicated that the highest exposure never exceeds 5.42% of the aRfD at the 95<sup>th</sup> percentile.

The chronic reference dose (cRfD) of 0.097 mg/kg bwt/day (chronic NOAEL with a 100-fold uncertainty factor) was used to assess chronic dietary exposure.

**Seed treatment use.** Bayer's chronic dietary analysis estimated the percent of the cRfD and corresponding MOE for the overall U.S. population (all seasons) and the following subpopulations: all infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), females (13–19 years), females (13–50 years), males (13–19 years), males (>20 years), and seniors (>55 years). In this analysis, all evaluated population subgroups had an exposure equal to 0% of the cRfD. The corresponding MOE was >1 million.

**Foliar application use.** Tomen has conducted a chronic Tier 1 analysis and the results indicated that the highest exposure never exceeds 8.7% of the cRfD at the 95<sup>th</sup> percentile.

i. **Food.** See above discussion.

ii. **Drinking water.** For drinking water, the models SCI-GROW (ground water), and generic expected environmental concentration (GENEEC) (surface water), were selected to calculate the potential exposure of TM-444 in drinking water. Both short-term (acute) and long-term (chronic) exposures were estimated with respect to foliar uses on apples and pears. The predicted ground water concentrations for foliar application of apples and pears were 1.17 and 1.30  $\mu$ /L, respectively. The highest estimated acute and chronic exposures from surface water were 9.10 and 3.07  $\mu$ /L, respectively. Based on the standard

exposure scenarios for drinking water (70kg adult- 2L/day; 10 kg child- 1L/day), the potential human exposure and risk can be estimated. Using the acute (0.60 mg/kg/day) and chronic (0.097 mg/kg/day) reference doses (RfD), the human risk from exposure to TM-444 in drinking water is estimated. The risk to adults and children from ground water exposure ranged from 0.006 to 0.019% of the acute RfD and from 0.038 to 0.134% of the chronic RfD; from surface water, the estimated risk ranged from 0.039% to 0.152% of the acute RfD and 0.081 to 0.316% of the chronic RfD respectively.

2. **Non-dietary exposure.** Clothianidin is currently not registered for use on any residential non-food site. Therefore, residential exposure to clothianidin residues will be through dietary exposure only.

#### D. Cumulative Effects

There is no information available to indicate that toxic effects produced by clothianidin are cumulative with those of any other compound.

#### E. Safety Determination

1. **U.S. population.** Using the conservative exposure assumptions described above and based on the completeness of the toxicity data, it can be concluded that total aggregate exposure to clothianidin from all proposed uses will be less than 9% of the RfD for the overall U.S. population. All evaluated population subgroups had an exposure less than 9% of the RfD. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Thus, Arvesta believes that it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to clothianidin residues.

2. **Infants and children.** In assessing the potential for additional sensitivity of infants and children to residues of clothianidin, the data from developmental toxicity studies in both the rat and rabbit, a two-generation reproduction study in rats and a developmental neurotoxicity study in rats have been considered.

The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through

two generations, as well as any observed systemic toxicity.

The developmental neurotoxicity studies evaluate the neurobehavioral and neurotoxic effects on the developing animal resulting from the exposure of the mother. FFDCA section 408 provides that EPA may apply an additional uncertainty factor for infants and children based on the threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity data base. Based on the current toxicological data requirements the toxicology data base for clothianidin relative to prenatal and postnatal development is complete, including the developmental neurotoxicity study. None of the studies indicated the offsprings to be more sensitive. All effects were secondary to severe maternal toxicity. The RfD for clothianidin was calculated using the NOAEL of 9.7 mg/kg bw/day from the two-year chronic/oncogenicity study. This NOAEL is lower than the NOAEL from the two-generation reproduction study, the developmental studies, and the developmental neurotoxicity study. Moreover, using a toxicologically justified UF of 100, the RfD for a non-oncogenic clothianidin was established at a level 0.097 mg/kg/day, a value that offers a measure of safety that is the highest among the other alternative compounds for control of apple and pear pests.

#### F. International Tolerances

No CODEX maximum residue levels (MRL's) have been established for residues of clothianidin on any crops at this time.

[FR Doc. 03-32205 Filed 12-30-03; 8:45 am]  
BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OW-FRL-7605-2]

### National Recommended Water Quality Criteria for the Protection of Human Health

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability.

**SUMMARY:** Pursuant to section 304(a) of the Clean Water Act (CWA), the Environmental Protection Agency (EPA) is announcing the availability of updated national recommended water quality criteria for the protection of human health for the following fifteen pollutants: chlorobenzene; cyanide; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,1-dichloroethylene; 1,3-

dichloropropene; endrin; ethylbenzene; hexachlorocyclopentadiene; lindane; thallium; toluene; 1,2-transdichloroethylene; 1,2,4-trichlorobenzene; and vinyl chloride.

The criteria are based on EPA's 2000 methodology for deriving human health water quality criteria and supercede criteria for these chemicals that the Agency published before this notice.

EPA's recommended section 304(a) water quality criteria are guidance to States and authorized Tribes in adopting water quality standards for protecting human health. They are also a scientific basis for developing controls of discharges or releases of pollutants. They are guidance to EPA for promulgating Federal regulations under CWA section 303(c), when such action is necessary.

Under the CWA and its implementing regulations, States and authorized Tribes are to adopt water quality criteria to protect designated uses (e.g., public water supply, recreational use, industrial use). EPA's recommended human health water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized Tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality standards that differ from these recommendations.

**ADDRESSES:** Copies of documents specifically referenced in this notice and scientific views received are in Docket ID No. OW-2002-0054. Materials in the public docket are available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Office of Water Docket is (202) 566-2426. A reasonable fee will be charged for copies. An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets, at <http://www.epa.gov/edocket/>. Once in the system, select "search," then key in the appropriate docket identification number.

**FOR FURTHER INFORMATION CONTACT:** Cindy Roberts, Health and Ecological Criteria Division (4304T), U.S. EPA, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460; (202) 566-1124; [roberts.cindy@epa.gov](mailto:roberts.cindy@epa.gov).

## SUPPLEMENTARY INFORMATION:

### General Information

#### A. Interested Entities

Entities potentially interested in today's notice are those that produce, use, or regulate chlorobenzene; cyanide; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,1-dichloroethylene; 1,3-dichloropropene; endrin; ethylbenzene; hexachlorocyclopentadiene; lindane; thallium; toluene; 1,2-transdichloroethylene; 1,2,4-trichlorobenzene; and vinyl chloride. Categories and entities interested in today's notice include:

| Category   | Examples of interested entities  |
|--|--|
| States, Authorized Tribes, and Jurisdictional Governments. | NPDES Authorized States, Tribes and Jurisdictions.   |
| Industry .....   | Industries discharging pollutants to surface waters or to publicly-owned treatment works discharging pollutants to surface waters. |
| Municipalities .....                                       | Publicly-owned treatment works discharging pollutants to surface waters.   |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this notice. This table lists the types of entities that EPA is now aware could potentially be interested in this notice. Other types of entities not listed in the table could also be interested.

#### B. How Can I Get Copies of the National Recommended Water Quality Criteria for the Protection of Human Health and Other Related Information?

1. *Docket.* EPA has established an official public docket for this notice under Docket ID No. OW-2002-0054. The official public docket consists of the documents specifically referenced in this notice, any public scientific views received, and other information related to this announcement. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public

Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Office of Water Docket is (202) 566-2426. A reasonable fee will be charged for copies.

2. *Electronic Access.* You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to view scientific views submitted by the public, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section B.1. Once in the system, select "search," then key in the appropriate docket identification number.

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### I. Background Information

#### A. What Are Human Health Water Quality Criteria?

Human health water quality criteria are numeric values that describe ambient water concentrations that protect human health from the harmful effects of pollutants in ambient water. These criteria are developed under CWA section 304(a) and are based solely on data and scientific judgments about the relationship between pollutant

concentrations and environmental and human health effects. Human health water quality criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water.

CWA section 304(a)(1) requires EPA to develop and publish and, from time to time, revise criteria for water quality that accurately reflect the latest scientific knowledge. EPA's recommended section 304(a) water quality criteria provide guidance to States and authorized Tribes in adopting water quality standards for protection of human health and can be used as a scientific basis for developing controls of discharges or releases of pollutants. The criteria also provide guidance to EPA when promulgating Federal regulations under CWA section 303(c), when such action is necessary.

#### *B. How Is the 2000 Human Health Methodology Used?*

In November 2000, EPA published the revised *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (EPA-822-B-00-004, October 2000; hereafter referred to as the "2000 Human Health Methodology"). Before this, the Agency developed recommended human health water quality criteria using the 1980 *Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapter of the Consent Decree Water Criteria Documents* (45 FR 79347, called the "1980 Methodology"). The 2000 Human Health Methodology incorporates significant scientific advances that have occurred over the last two decades, particularly in the areas of cancer and noncancer risk assessments (using new information, procedures, and published Agency guidelines), exposure assessments (using new studies on human intake and exposure patterns, and new Agency guidelines), and methodologies to estimate bioaccumulation in fish. EPA will use the 2000 Human Health Methodology to develop new section 304(a) water quality criteria for additional pollutants and to revise existing section 304(a) water quality criteria. The 2000 Human Health Methodology is an important part of EPA's efforts to improve the quality of the Nation's waters and strengthen the overall scientific basis of water quality criteria. Furthermore, the 2000 Human Health Methodology will help States and authorized Tribes address their unique water quality issues and make risk management decisions to protect human health consistent with CWA

section 303(c). The 2000 Human Health Methodology provides a detailed means for developing water quality criteria, including systematic procedures for evaluating cancer risk, noncancer health effects, human exposure, and bioaccumulation potential in fish.

#### *C. How Does EPA Use Its Recommended Water Quality Criteria?*

Water quality standards generally consist of designated uses (e.g., public water supply, recreational use, industrial use), water quality criteria to protect those uses, a policy for antidegradation (that maintains and protects existing uses and water quality conditions), and general policies for application and implementation of water quality standards. As part of the water quality standards triennial review process defined in CWA section 303(c)(1), States and authorized Tribes are responsible for maintaining and revising water quality standards. Section 303(c)(1) requires States and authorized Tribes to review and, if appropriate, modify their water quality standards at least once every three years. EPA's recommended section 304(a) water quality criteria may form the basis for Agency decisions, both regulatory and non-regulatory, until they are superseded by EPA's publication of new or revised section 304(a) water quality criteria. These recommended water quality criteria are used in the following ways:

- (1) as guidance to States and authorized Tribes in adopting water quality standards,
- (2) as guidance to EPA in promulgating Federal water quality standards,
- (3) to interpret a State's narrative water quality standard (in the absence of a State adopted numeric standard) in order to establish National Pollutant Discharge Elimination System (NPDES) water quality-based permit limits, and
- (4) for all other purposes of CWA section 304(a).

Two distinct purposes are served by the section 304(a) water quality criteria. The first is as guidance to the States and authorized Tribes in the development and adoption of water quality criteria that will protect designated uses for their waters. The second is as guidance for promulgation of Federal water quality criteria for States and authorized Tribes, when such action is necessary under the terms of the CWA.

#### *D. What Is the Relationship Between 304(a) Criteria and Your State or Tribal Water Quality Standards?*

States and authorized Tribes must adopt water quality criteria that protect

designated uses pursuant to CWA section 303(c)(2)(A). Protective criteria are based on a sound scientific rationale and must contain sufficient parameters or components to protect the designated uses. Water quality criteria may be expressed in either narrative or numeric form. States and authorized Tribes may use one of four approaches when adopting water quality criteria:

- (1) Establish numerical values based on section 304(a) recommended water quality criteria,
- (2) Modify the section 304(a) recommended water quality criteria to reflect site-specific conditions,
- (3) Use other scientifically defensible methods to derive protective water quality criteria, and
- (4) Establish narrative water quality criteria where numeric criteria cannot be determined or to supplement numeric water quality criteria.

EPA encourages States and authorized Tribes to use EPA's section 304(a) water quality criteria as guidance when adopting water quality standards consistent with CWA section 303(c) and the Federal regulations at 40 CFR part 131.

#### *E. May States and Authorized Tribes Adopt Water Quality Criteria Based on Local Conditions?*

EPA encourages States and authorized Tribes to develop and adopt water quality criteria to reflect local and regional conditions. In the 2000 Human Health Methodology, EPA published default values for risk level, fish intake, drinking water intake, and body weight for use by EPA, States or authorized Tribes in deriving human health water quality criteria. EPA believes these default values result in water quality criteria that protect the general population. States and authorized Tribes may also use these default values for their own water quality criteria, or they may use other values more representative of local conditions if they have data supporting the alternative values.

#### *F. How Does the Review and Approval of State and Tribal Water Quality Standards Affect Water Quality Criteria Adopted by States and Authorized Tribes?*

In 2000, EPA published new regulations addressing its review and approval of water quality standards adopted by States and authorized Tribes (see 65 FR 24642; April 27, 2000.) Under the new regulations, (codified at 40 CFR 131.21(c)-(f)), State or authorized Tribal water quality standards that were adopted by law or regulation before May 30, 2000, are in

effect for CWA purposes unless superseded by replacement Federal water quality standards (see 40 CFR 131.21(c)). However, under the new regulation, State or authorized Tribal water quality criteria adopted into State or Tribal law or regulation on or after May 30, 2000, are in effect for CWA purposes only after EPA approves any new or revised water quality standards. Therefore, new or revised water quality criteria adopted by States or authorized Tribes would not take effect for CWA purposes until after EPA approves them.

**II. Human Health Water Quality Criteria Revisions**

*A. What Are the Criteria Revisions?*

Today, EPA is announcing the availability of national recommended water quality criteria for the protection of human health for the following fifteen pollutants: Chlorobenzene; cyanide; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,1-dichloroethylene; 1,3-dichloropropene; endrin; ethylbenzene;

hexachlorocyclopentadiene; lindane; thallium; toluene; 1,2-transdichloroethylene; 1,2,4-trichlorobenzene; and vinyl chloride. The updated criteria are based on EPA's new methodology for deriving human health water quality criteria (i.e., the 2000 Human Health Methodology), and they supercede criteria previously published by the Agency.

These criteria represent partial updates of the section 304(a) water quality criteria, as described in both the draft Methodology revisions and the **Federal Register** notice that accompanied the final Methodology (65 FR 66444; November 3, 2000). EPA believes that updating a limited number of components for which there are available data or improved science (i.e., a partial update) is a reasonable and efficient way to more frequently publish revised section 304(a) water quality criteria. EPA has also described its process for publishing revised criteria [see *National Recommended Water Quality Criteria—Correction* (64 FR 19781; or EPA 822-Z-99-001) or the

**Federal Register** notice for the final Methodology (65 FR 66444)].

Because recalculation of these fifteen criteria resulted in significant changes, EPA issued a **Federal Register** notice soliciting scientific views on the criteria on December 27, 2002 (67 FR 79091). This **Federal Register** Notice was issued in accordance with the published process for revising section 304(a) water quality criteria. EPA considered the scientific views received in response to the December 27, 2002, **Federal Register** notice. All criteria concentrations in this Notice are the same as those published in the December 27, 2002 (67 FR 79091), with the exception of the criterion for protecting human health from consumption of organism only for cyanide. (See section B, response to Scientific view b, Incidental ingestion should be considered when deriving human health water quality criteria for toxic pollutants with a low BCF.) Table II-1 presents the updated criteria, as well as the components used in their derivation (e.g., bioconcentration factor, relative source contribution).

TABLE II-1.—REVISED HUMAN HEALTH WATER QUALITY CRITERIA

| Priority pollutant                | CAS No. | Human health water quality criteria for consumption of: |                      | Components  |
|-----------------------------------|---------|---|----------------------|---|
|                                   |         | Water + organism (ug/L)                                 | Organism only (ug/L) |   |
| Thallium .....                    | 7440280 | 0.24  | 0.47                 | RfD = 6.8E-5, BCF = 116 (RfD listed is for thallium (I) sulfate 7446-18-6), RSC = 20%, FI = 17.5. |
| Cyanide .....                     | 57125   | 140   | *140                 | RfD = 2E-2, BCF = 1, RSC = 20%, FI = 17.5.  |
| Chlorobenzene .....               | 108907  | 130   | 1,600                | RfD = 2E-2, BCF = 10.3, RSC = 20%, FI = 17.5.   |
| 1,1-Dichloroethylene .....        | 75354   | 330   | 7,100                | RfD = 5E-2, RSC = 20%, BCF = 5.6, FI = 17.5.  |
| 1,3-Dichloropropene .....         | 542756  | 0.34  | 21                   | *q1 = 0.1, BCF = 1.9, FI = 17.5.  |
| Ethylbenzene .....                | 100414  | 530   | 2,100                | RfD = 1E-1, BCF = 37.5, RSC = 20%, FI = 17.5.   |
| Toluene .....                     | 108883  | 1,300   | 15,000               | RfD = 2E-1, BCF = 10.7, RSC = 20%, FI = 17.5.   |
| 1,2-Trans-Dichloro-ethylene ..... | 156605  | 140   | 10,000               | RfD = 2E-2, BCF = 1.58, RSC = 20%, FI = 17.5.   |
| Vinyl Chloride .....              | 75014   | 0.025   | 2.4                  | *q1 = 1.4 (LMS exposure from birth), BCF = 1.17, FI = 17.5.                                       |
| 1,2-Dichlorobenzene .....         | 95501   | 420   | 1,300                | RfD = 9E-2, BCF = 55.6, RSC = 20%, FI = 17.5.   |
| 1,4-Dichlorobenzene .....         | 106467  | 63  | 190                  | ADI = 1.34E-2, (ADI for 1,2-DCB used), BCF = 55.6, RSC = 20%, FI = 17.5.                          |
| Hexachlorocyclo-pentadiene .....  | 77474   | 40  | 1,100                | RfD = 6E-3, BCF = 4.34, RSC = 20%, FI = 17.5.   |
| 1,2,4-Trichloro-benzene .....     | 120821  | 35  | 70                   | RfD = 1E-2, BCF = 114, RSC = 20 %, FI = 17.5.   |
| gamma-BHC (Lindane) .....         | 58899   | 0.98  | 1.8                  | RfD= 3E-4, BCF = 130, RSC= 20%, FI = 17.5.  |
| Endrin .....                      | 72208   | 0.059   | 0.060                | RfD = 3E-4, BCF = 3970, RSC = 20%, FI = 17.5.   |

RfD = reference dose; q1\* = cancer potency factor; ADI = allowable daily intake; BCF = bioconcentration factor; RSC = relative source contribution; FI = fish intake

\*This recommended water quality criterion is expressed as total cyanide, even though the IRIS RfD we used to derive the criterion is based on free cyanide. The multiple forms of cyanide that are present in ambient water have significant differences in toxicity due to their differing abilities to liberate the CN-moiety. Some complex cyanides require even more extreme condition than refluxing with sulfuric acid to liberate the CN-moiety. Thus, these complex cyanides are expected to have little or no 'bioavailability' to humans. If a substantial fraction of the cyanide present in a water body is present in a complexed form (e.g., Fe<sub>4</sub>[Fe(CN)<sub>6</sub>]<sub>3</sub>), this recommended criterion may be over conservative.

EPA received much support for revising criteria based on partially updated components of the criteria equations as a way of increasing the frequency of scientific improvements to the nationally recommended criteria. For EPA to consider a water quality criterion revision based on a partial

update to be acceptable, the components being used in the update should be comprehensive (e.g., a revised reference dose or cancer dose-response assessment), stand alone, and be based on new national or local data. The recalculation of all fifteen water quality criteria integrates the updated national

default freshwater/estuarine fish consumption rate of 17.5 grams/day. Thirteen of the criteria were calculated using a previously-determined relative source contribution (RSC) value from the national primary drinking water standards for the same chemicals. EPA also incorporated into the recalculations

a new cancer potency factor ( $q1^*$ ) for 1,3-dichloropropene and vinyl chloride, and a new reference dose (RfD) for 1,1-dichloroethylene, hexachlorocyclopentadiene, and lindane. These values were already published in the Agency's Integrated Risk Information System (IRIS). Both an RfD and  $q1^*$  are available in IRIS for 1,3-dichloropropene and vinyl chloride. Because it resulted in more protective criteria, EPA used the  $q1^*$  to derive the criteria in these cases rather than the RfD.

We derived the water quality criteria presented here with bioconcentration factors (BCFs) or field-measured bioaccumulation factors (BAFs) based on the 1980 Methodology. These values are consistent with those used to promulgate human health water quality criteria for priority toxic pollutants in rules such as the 1992 National Toxics Rule and the 2000 California Toxics Rule.

#### *B. What Are EPA's Responses to the Scientific Views Received on the Criteria Revisions?*

This section summarizes the scientific views received in response to the December 27, 2002, **Federal Register** Notice. It also presents EPA's responses to the scientific views.

##### 1. 2000 Human Health Methodology

a. Support application of EPA's new methodology for deriving human health water quality criteria.

*Scientific View*—One submitter expressed support of EPA's application of the new human health methodology, including using more current estimates of daily fish intake, relative source contribution (for noncarcinogenic effects), and updated toxicological data.

*Response*—EPA acknowledges and appreciates the submitter's support.

b. Incidental ingestion should be considered when deriving human health water quality criteria for toxic pollutants with a low BCF.

*Scientific View*—One submitter indicated that EPA should consider acute and chronic effects from incidental ingestion of water when deriving human health water quality criteria associated with the consumption of "organisms only" for toxic pollutants with a low BCF. It is possible to exceed the RfD based on chronic toxicity when incidental ingestion occurs at the criterion concentration established for protecting human health for consumption of organisms only. Before finalizing the criteria revisions, EPA should compare the potential for acute toxicity from incidental ingestion of acutely toxic

substances to the threshold for acute toxicity. The submitter uses cyanide as an example of a chemical for which acute and chronic effects from incidental ingestion of water should be considered as we develop human health water quality criteria.

*Response*—In developing the 2000 Human Health Methodology, EPA reviewed estimates of incidental water ingestion rates averaged over time. Based on this review, EPA generally believes that the averaged amount is negligible and will not impact the chemical criteria values that represent both drinking water and fish ingestion, unless (as indicated in the 2000 Methodology) the chemical exhibits minimal or no bioaccumulation potential.

EPA expects that the cyanide criterion for consumption of organisms only established based on the 2000 Human Health Methodology is generally protective of human health. However, cyanide is an acutely toxic substance (with a low bioaccumulation potential), and the resulting criterion of 16,000 ug/L derived for consumption of organism only may not protect humans from acutely toxic effects. Thus, EPA considers it prudent health policy to establish the criterion concentration for consumption of organisms only at the same level as the value for protecting human health for consumption of water and organisms (140 ug/L). The EPA's IRIS RfD that we used to derive the criterion is based on free cyanide. If a substantial fraction of the cyanide present in a water body is present in a complexed form (e.g.,  $Fe_4[Fe(CN)_6]_3$ ), this recommended criterion may be overly conservative. State and authorized Tribes, however, have the discretion to modify section 304(a) criteria to reflect site-specific conditions.

c. Future updates of human health water quality criteria should consider additional exposure routes.

*Scientific view*—A submitter supported EPA's plans to include additional exposure routes resulting from recreational activities (e.g., dermal, inhalation).

*Response*—EPA appreciates the submitter's support. As stated in the published draft methodology revisions (65 FR 66444; November 3, 2000) and in *Response to Peer Review Comments on Draft Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (EPA-822-R-00-009, August 2000), EPA acknowledges that the potential for inhalation and dermal exposures exist, and an approach to account for them in the context of developing individual

water quality criteria is appropriate. EPA intends to refine the 2000 Human Health Methodology in the future to incorporate guidance on inhalation and dermal exposures.

d. National default BCFs and BAFs should not be used in the derivation of water quality criteria.

*Scientific view*—A submitter stated that the 15 proposed human health water quality criteria are based, in part, on using national default BCFs or BAFs without demonstrating that a statistically and ecologically significant correlation exists between the compound in the water column and levels found in fish tissues. The submitter uses methylmercury as an example of a chemical for which that correlation has not yet been demonstrated. As a consequence, the submitter strongly objects to the use of BCFs or BAFs in deriving the criteria. The submitter further stated that EPA should notify States and authorized Tribes not to adopt the revised criteria into State or Tribal standards until they can confirm a statistically significant (and important) relationship between water column concentrations and fish tissue concentrations.

*Response*—Using national default BCFs for water quality criteria began in 1980 and is necessary to ensure that criteria related to human ingestion of fish and shellfish will be protective of the consumer human populations who eat them. The BCF values determined for the water quality criteria represented the best scientific information available at the time. BCFs for nonionic organic chemicals that were determined from Veith *et al.* (1979) are based on a statistically significant correlation between experimentally determined chemical concentrations in water and fish tissues. We describe in detail the scientific basis for applying this data in the 1980 Ambient Water Quality Criteria National Guidelines (45 FR 79347).

EPA recognizes that many scientific advances have occurred in the area of bioaccumulation since it published the 1980 Methodology. As a result, EPA has revised the bioaccumulation portion of the 1980 Methodology to reflect the current state of science and to improve accuracy in assessing bioaccumulation for setting 304(a) criteria. EPA's *Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health (2000)* (65 FR 66444; hereafter referred to as the "2000 Methodology") contains the revised procedures for incorporating bioaccumulation in ambient water quality criteria (AWQC) and a summary of the key changes. EPA will publish more detailed information on the BAF

methodology in the near future (*Technical Support Document Volume 2: Development of National Bioaccumulation Factors*). We developed the approaches to deriving bioaccumulation factors and applying them in AWQC presented from a process that included extensive review from EPA's Science Advisory Board, peer review workshops, and stakeholder meetings (65 FR 6644).

EPA's framework deriving bioaccumulation factors is designed to account for chemical, biological and ecological attributes. For example, we provide separate procedures for deriving national BAFs depending on the type of chemical (*i.e.*, nonionic organic, ionic organic, inorganic and organometallic). More specifically, EPA's framework recognizes that the derivation of BAFs for organometallic chemicals differs in several ways from procedures for organic chemicals. For example, there are no generic bioaccumulation models that can be used to predict BAFs for organometallic chemicals as a whole; therefore, EPA's preferred approach for deriving national BAFs for such chemicals is to use empirical field data.

EPA took this approach in deriving draft national BAFs for methylmercury (see *Water Quality Criterion for the Protection of Human Health: Methylmercury* (EPA-823-R-01-001, January 2001)). We found the empirically-derived draft methylmercury BAFs to be variable, reflecting the influences of various biotic factors and abiotic factors on methylmercury bioaccumulation that were not well understood at that time. EPA acknowledged that these factors resulted in uncertainty as to the ability of the BAFs to accurately predict bioaccumulation of methylmercury across the waters of the United States. However, in this same document, EPA noted that this is not the case for other highly bioaccumulative pollutants (*i.e.*, non-organometallics). For such pollutants, EPA has methods that improve the predictive capability of empirically-derived or model-predicted BAFs.

When it conducts a full re-evaluation of the human health water quality criteria for the chemicals included in this Notice, EPA will evaluate the best available evidence concerning BAF values. EPA will develop national BAF values to the extent possible given the best available data at the time. Where derivation of National BAFs is not possible, EPA's 2000 Methodology encourages States and authorized Tribes to derive BAFs that are specific to regions or waterbodies as appropriate.

e. Scientific validity of using cancer potency factors or RfDs to define thresholds of unacceptable adverse effects is questionable.

*Scientific view*—One submitter questioned the scientific validity of using cancer potency factors or RfDs to define thresholds of unacceptable adverse effects. EPA should explicitly address the "scientific gray area" that exists between human health effects and RfDs and a benchmark dose or the lowest observed effect level on which an RfD might be based.

*Response*—As discussed in *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (EPA-822-B-00-004, October 2000), human health water quality criteria are designed to minimize the risk of adverse effects to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and eating fish from surface waters.

The water quality criteria are based on chronic health effects data (both cancer and noncancer). However, the criteria also are intended to protect against adverse effects not only for the general population over a lifetime of exposure, but also for special populations (*e.g.*, sports fishers, children, elderly) who have an increased risk of receiving a dose that would elicit adverse effects due to their high water- or fish-intake rates or their biological sensitivities. Neither the benchmark dose nor a lowest observed effects level represent a "threshold" for response in the human or animal populations. Instead, those values typically are associated with a small proportional response level for the populations in question. EPA acknowledges the possibility that other populations might be more sensitive than those examined.

The Agency fully documents the derivation of its cancer potency factors and RfDs in IRIS. Those values were derived using the Agency guidelines for risk assessment, extensive peer review, and the best available information at the time the values were developed. The Agency continues to review and update the human health effects data in IRIS to ensure it considers the most current literature. That process, however, takes time. The IRIS Web (<http://www.epa.gov/iris/>) site describes EPA's policy on the "scientific gray areas" that reflect the use of uncertainty factors to cover certain types of data gaps.

## 2. EPA Should Adopt a Fish Tissue-Based Criteria in Lieu of the Proposed Water Column Criteria

*Scientific view*—EPA should derive fish tissue criteria, rather than water

column concentrations, for the 15 compounds to avoid the scientific deficiencies related to the inappropriate use of BCFs and BAFs. Compliance monitoring and site-specific adjustments also are simplified when criteria are based on fish-tissue measurements in lieu of water column criteria. The submitter also requested a table of the intermediate fish tissue levels used in (or derived from) the calculation of the proposed water column criteria.

*Response*—For the most part, EPA has published water column concentrations as their recommended water quality criteria values for protection of human health. The recent exception being the fish tissue concentration for methylmercury (see 66 FR 1344, January 8, 2001). When the new methylmercury criterion was published, EPA withdrew its previous ambient human health water quality criteria for mercury as the recommended section 304(a) water quality criteria. At that time, EPA also recognized that this approach differed from the traditional water column criteria approach and suggested ways to relate the fish and shellfish tissue criterion to concentrations of methylmercury in the water column. We must relate tissue concentrations to water column concentrations in order to use the criterion to establish discharge limits for point sources. Fish tissue criteria can be developed and potentially simplify compliance monitoring and site-specific adjustments, yet this does not eliminate the need to develop BAFs.

Using national BAFs is a scientifically valid approach to deriving national water quality criteria. EPA encourages States and authorized Tribes to develop BAFs based on field-measured data from local/regional fish, whenever possible, when developing their own water quality standards.

The 15 revised human health criteria do not incorporate BAFs, a component of the new methodology; rather, the revised criteria are based on previously-developed BCFs. Thus, we have not estimated intermediate fish tissue concentrations.

## 3. EPA Should Provide All Numeric Factors Used in the Derivation of the Proposed Criteria

*Scientific view*—One submitter stated that EPA should provide information and references for all components needed to calculate the proposed criteria, including  $K_{ow}$  values and food chain multipliers.

*Response*—EPA included all basic parameters necessary for deriving the criteria in the December 27, 2002,

**Federal Register** notice announcing the proposed revisions (67 FR 79091). These parameters include: BCFs, fish consumption rate, body weight, reference dose or cancer potency factor, and relative source contribution. You can find information relevant to the derivation of these basic parameters (e.g.,  $K_{ow}$  values used in the derivation of BCFs) in other data sources such as EPA's criteria documents.

The revised human health criteria EPA developed use the BCF values derived from the 1980 Ambient Water Quality Criteria National Guidelines (45 FR 79347). We did not use food chain multipliers in the 1980 Methodology and, therefore, did not use them in deriving the proposed criteria. Rather, the proposed criteria rely on previously-derived BCFs which may have been derived from lab or field studies. Even though these BCFs emphasize bioconcentration, in some instances they may reflect trophic level transfers but not through the use of food chain multipliers.

#### 4. EPA Should Publish All Proposed Changes to the Human Health Water Quality Criteria in the **Federal Register**

*Scientific view*—One submitter stated that EPA should publish all proposed changes to the human health water quality criteria in the **Federal Register**. In this way, dischargers and other affected parties will be aware of upcoming changes that will affect permits and other activities.

*Response*—EPA described its process for publishing revised criteria in *National Recommended Water Quality Criteria—Correction* (64 FR 19781; or EPA 822-Z-99-001) and the **Federal Register** notice for the final methodology (65 FR 66444). EPA specifically stated that, when making minor revisions to existing criteria based on new information about individual components of the criteria, the Agency will publish the recalculated criteria directly as the Agency's national recommended water quality criteria. This is a reasonable and efficient way to more frequently publish revised section 304(a) criteria. Based on this approach, EPA partially revised 83 national recommended water quality criteria for the protection of human health. EPA published these updated national recommended water quality criteria in a compilation entitled *National Recommended Water Quality Criteria: 2002* (EPA-822-02-047).

EPA also revised 15 more national recommended water quality criteria for the protection of human health. Although the revision of these criteria represent a partial update of the section

304(a) criteria, EPA decided to solicit scientific views on the criteria because applying the new methodology resulted in significant changes (67 FR 79091; December 27, 2002).

#### 5. The Criteria Compilation Should Clearly Articulate That the Recommended Criteria Are Available for States To Use, as Appropriate, in Adopting Their Water Quality Criteria

*Scientific view*—A submitter stated that the 2000 Human Health Methodology encourages States to use local fish consumption rates to establish site-specific criteria rather than default fish consumption rates. However, without site-specific fish consumption rates, States cannot develop the most accurate criteria. Therefore, the criteria compilation should clearly articulate that States are not required to adopt EPA's recommended criteria, but that EPA's recommended criteria are available, as appropriate, when adopting criteria.

*Response*—CWA section 304(a)(1) requires EPA to develop and publish criteria for water quality that accurately reflect the latest scientific knowledge. Under this authority, EPA publishes national criteria that are recommendations to States and authorized Tribes in adopting water quality standards. These criteria are based on national default parameters, such as fish ingestion rates. Nevertheless, as stated in the *National Recommended Water Quality Criteria: 2002* (EPA-822-02-047) compilation, "State and Tribal decision-makers have the discretion to adopt approaches on a case-by-case basis that differ from this guidance when appropriate." In addition, the 2002 compilation document explains that:

"States and authorized Tribes have four options when adopting water quality criteria for which EPA has published section 304(a) criteria. They can: (1) Establish numerical values based on recommended section 304(a) criteria; (2) adopt section 304(a) criteria modified to reflect site-specific conditions; (3) adopt criteria derived using other scientifically defensible methods; or (4) establish narrative criteria when numeric criteria cannot be determined (40 CFR 131.11)."

Thus, EPA clearly stated that States and authorized Tribes are not required to adopt EPA national recommended water quality criteria, and that States and authorized Tribes have the discretion to derive criteria based on site-specific considerations such as local fish consumption rates.

#### 6. Vinyl Chloride

a. The proposed human health water quality criteria for vinyl chloride are too low.

*Scientific view*—A submitter indicated that improper methods, overly conservative assumptions, and data quality deficiencies result in the proposed human health water quality criteria for vinyl chloride being too low.

*Response*—In deriving the water quality criteria for vinyl chloride, EPA applied the 2000 Human Health Methodology. In developing this methodology, EPA solicited and incorporated input from many sources, including the EPA Science Advisory Board, several peer review workshops, and the public. EPA believes that the resulting methodology accurately reflects the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare that can be expected when pollutants are present in any body of water. Thus, the human health water quality criteria for vinyl chloride accurately reflect the relationship between vinyl chloride concentrations and human health effects.

The recommended water quality criteria for vinyl chloride are guidance for States and authorized Tribes to establish water quality standards. State and Tribal decision-makers have the discretion to adopt approaches on a case-by-case basis that differ from this guidance when appropriate.

b. EPA should use a central estimate as a point of departure in deriving vinyl chloride criteria.

*Scientific view*—Two submitters stated that the revised vinyl chloride human health water quality criteria for consumption of water and organism and consumption of organisms only are too low because EPA used overly conservative assumptions in their derivation. Risk-specific doses derived based on linear low-dose extrapolations using the lower 95 percent confidence limit on a dose associated with a 10 percent extra risk, or,  $LED_{10}$ , as the point of departure should not be used to derive criteria. Rather, risk-specific doses based on a central estimate, such as a dose associated with a 10 percent extra risk, or  $ED_{10}$ , should be used as a point of departure.

EPA's rationale for using the  $LED_{10}$  as the point of departure for model-based dose-response extrapolations in the 1996 proposed guidelines for carcinogen risk assessment is very weak. EPA did not hear the advice from peer review workshops on benchmark dose and the proposed cancer guidelines

recommending the use of a central estimate (ED<sub>10</sub>) point of departure.

EPA's decision to use an LED<sub>10</sub>, as opposed to an ED<sub>10</sub>, in deriving revised human health criteria for vinyl chloride is inconsistent with EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency and the Information Quality Act (IQA). EPA's science policy decision to use the LED<sub>10</sub>, instead of the ED<sub>10</sub>, introduces significant uncertainty in the risk assessment that underlies the water quality criteria derivations, which is in violation of the IQA. The submitter requested that we correct this information.

*Response*—The 2000 Human Health Methodology includes toxicological and exposure assessment parameters derived from scientific analysis, science policy, and risk management decisions, including the 1986 cancer guidelines [see *Guidelines for Carcinogen Risk Assessment* (51 FR 33992)] and principles from the 1999 draft revised cancer guidelines [see *1999 Guidelines for Carcinogenic Risk Assessment—Review Draft* (NCEA-F-0644, July 1999)]. These principles arise from scientific discoveries about cancer made in the last 15 years and from EPA policy supporting full characterization of hazard and risk for both the general population and potentially sensitive groups like children.

In particular, EPA's 1999 draft revised cancer guidelines gave a rationale for selecting point of departures (PODs). For quantitative modeling of dose-response relationships in the observed range, the guidelines recommend calculating the lower 95 percent confidence limit on a dose associated with an estimated 10 percent increased tumor or relevant non-tumor response (LED<sub>10</sub>). The estimate of the LED<sub>10</sub> is used as the point of departure (POD) for low-dose extrapolation. This standard point of departure (LED<sub>10</sub>) is adopted as a matter of science policy to remain as consistent and comparable across different studies. It is also a convenient comparison point for noncancer endpoints. The rationale for using the LED<sub>10</sub> is that a 10 percent response is at or just below the limit of sensitivity for discerning a statistically significant tumor response in most long-term rodent studies and is also within the observed range for other toxicity studies. Using the lower limit takes experimental variability and sample size into account. Note that use of the lower 95 percent confidence limit on the ED<sub>10</sub> implies that, given the experimental parameters (e.g., sample size, variation

in response) of the study being used, there is a five percent chance or less that the "true" ED<sub>10</sub> would be lower than the LED<sub>10</sub>. For well-conducted studies with large numbers of animals, relatively close dose spacing, and little inherent variability in the animal responses, LED<sub>10</sub> values will be close to the central estimate of the ED<sub>10</sub> value. For studies that include smaller numbers of animals, wider dose spacing, and more variable responses in replicates at the same dose, the LED<sub>10</sub> value will be further removed from the ED<sub>10</sub> value. It is part of EPA's science policy to use the lower bound of a 95 percent confidence interval around a preferred value (e.g., central estimate of the ED<sub>10</sub>) as a point of departure to ensure that the criterion will be adequately protective, that is, that the experimental uncertainty is small (a few percent or less). The EPA's IRIS cancer assessment of vinyl chloride uses the LED<sub>10</sub> as the POD. EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA/260R-02-008, October 2002) indicated that EPA intends to specify the central estimate of human health risk when it is available. The ED<sub>10</sub> (central estimate) for vinyl chloride is not presented in IRIS. More recent IRIS entries do include the central estimate, but this was not the policy at the time vinyl chloride was completed. The requirement for its inclusion was instituted in the 2003 Standard Operating Procedures for IRIS.

c. The vinyl chloride MCL is a more appropriate benchmark level.

*Scientific view*—A submitter indicated that the current maximum contaminant level (MCL) for vinyl chloride of two parts per billion (ppb) which was developed under the Safe Drinking Water Act (SDWA) is a more appropriate benchmark level.

*Response*—The human health water quality criteria developed under CWA section 304(a) are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects. Unlike the MCLs, the criteria do not consider economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water. Thus, MCLs are not considered counterparts to water quality criteria.

d. The vinyl chloride water quality criterion for consumption of organisms should only be based on incidental ingestion of non-potable, recreational waters.

*Scientific view*—A submitter stated that the revised vinyl chloride human

health criteria for potable water was derived based on the assumption that people would drink two liters of surface water each day over a lifetime. Thus, surface water is effectively considered a public water supply. However, if the intended use of the water quality criteria is to set NPDES limits for potable waters not being used as public water supplies, then the water consumption assumption is overly conservative. Such waters serve only as recreational or occasional use water bodies, so that a value for incidental water ingestion would be more appropriate. For regulatory consistency, the water quality criteria for vinyl chloride for potable water supplies should be the same as the MCL.

*Response*—As required by CWA section 304(a), EPA develops water quality criteria that reflect the latest scientific knowledge on effects of pollutants on human health. States and authorized Tribes use the Agency's recommended section 304(a) water quality criteria to adopt enforceable water quality standards, including designating uses of a water body consistent with CWA section 101(a) (e.g., public water supply, fishing, recreation). In developing the 2000 Human Health Methodology, we made assumptions about exposure to contamination from consuming surface waters of the U.S. Our assumptions ensure that, if criteria are met in a water body designated with the uses specified in section 101(a), people can safely consume water from that water body. In order to ensure this, it is necessary to assume that all of the consumed water is taken from water bodies at the criteria level (i.e., contaminated to the maximum safe level).

The designated use inherent in the submitter's example is drinking water (potable water), even though the particular water body might not be used that way at the moment. Thus, the main issue in the view relates to the State's (or authorized Tribe's) assignment of designated use, not to numeric values for the national ambient water quality criteria for vinyl chloride.

Again, the human health water quality criteria developed under CWA section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Unlike the MCLs, the criteria do not consider economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water. MCLs are not counterparts to water quality criteria.

e. EPA's BCF for vinyl chloride is overstated and its water quality criterion

for consumption of organisms should only be based on incidental ingestion of non-potable, recreational waters.

*Scientific view*—One submitter stated that EPA derived its vinyl chloride human health criterion for consumption of organisms only using a bioconcentration factor (BCF) of 1.17. The submitter believes that this BCF is overstated because:

(1) This value is based on the assumption of equilibrium conditions between water and an organisms tissue, which is not the case because the compound is highly metabolized;

(2) the high volatility of vinyl chloride would contribute to its depuration during processing or cooking;

(3) the portions of the fish most likely to contain the compound, (*e.g.*, skin and fat) are not typically consumed by humans; and

(4) cooking would result in further off-gasing or destruction of the chemical.

Thus, we expect the potential for humans consuming aquatic organisms to be exposed to vinyl chloride to be negligible. Moreover, vinyl chloride does not biomagnify, and higher tropic level organisms consumed by humans would not contain elevated levels of vinyl chloride. EPA should derive its vinyl chloride criteria for consumption of organisms only based on exposure from incidental ingestion of non-potable recreational waters only.

*Response*—In updating its human health water quality criteria for vinyl chloride, EPA used the BCF derived from the 1980 Ambient Water Quality Criteria National Guidelines (45 FR 79347). The submitter is correct that, if a contaminant is readily metabolized in fish, the actual BCF might be less than estimated using the  $K_{LED_{ow}}$  method. EPA thanks the submitter for the information and will consider it when the Agency comprehensively updates the vinyl chloride criterion document to incorporate the BAF derivation procedures described in the 2000 Human Health Methodology.

#### C. Where Other Views Submitted?

We received a number of views on criteria that EPA was not revising, or the views expressed were not related to the science supporting the criteria derivations. EPA did not prepare responses addressing these views.

Dated: December 23, 2003.

**Geoffrey H. Grubbs,**

*Director, Office of Science and Technology.*

[FR Doc. 03-32211 Filed 12-30-03; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7604-7]

RIN 2040-ACXX

### Preliminary Effluent Guidelines Program Plan for 2004/2005

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

**ACTION:** Notice of preliminary effluent guidelines plan; request for comments.

**SUMMARY:** Today's notice presents and invites comment on EPA's preliminary Effluent Guidelines Program Plan for 2004/2005. Under the Clean Water Act (CWA), EPA establishes technology-based national regulations, termed "effluent guidelines," to reduce pollutant discharges from industrial facilities to waters of the United States. Section 304(m) of the Clean Water Act (CWA) requires EPA to publish an Effluent Guidelines Program Plan every two years. Today's notice has three purposes. First, it presents the results of EPA's annual review of the effluent guidelines that EPA has promulgated under CWA section 304(b). Second, it solicits public comment on the preliminary Effluent Guidelines Program Plan. Third, it describes and solicits comment on the analytical framework that EPA has employed to date in performing the annual review for 2003 and in developing today's preliminary Effluent Guidelines Program Plan. EPA had articulated an early form of this evolving analytical framework in the draft Strategy for National Clean Water Industrial Regulations, which EPA hopes to finalize concurrently with the Effluent Guidelines Program Plan in 2004.

**DATES:** EPA must receive comments on the preliminary Effluent Guidelines Program Plan for 2004/2005 by February 17, 2004. EPA will conduct a public meeting on Wednesday, January 28, 2004, from 9 a.m. to 12 p.m. Eastern Standard Time. For information on the location of the public meeting, see **ADDRESSES** section.

**ADDRESSES:** You can submit comments electronically, by mail, or through hand-delivery/courier. Please mail comments to the Water Docket, Environmental Protection Agency, Mail Code: 4101 T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460 or submit them electronically to <http://www.epa.gov/edocket/>. For more information on submitting comments, see section I.C. EPA will hold an informational public meeting for interested stakeholders in the EPA East Building, Room 1153 (also known as the "Great Room" or the

"Map Room"), 1201 Constitution Avenue, NW., Washington, DC. For more information on the details and location of the public meeting, see section I.F.

**FOR FURTHER INFORMATION CONTACT:** Mr. Carey A. Johnston at (202) 566-1014 or [johnston.carey@epa.gov](mailto:johnston.carey@epa.gov), or Mr. Tom Wall at (202) 566-1060 or [wall.tom@epa.gov](mailto:wall.tom@epa.gov).

#### SUPPLEMENTARY INFORMATION:

#### How Is This Document Organized?

The outline of the preliminary Effluent Guidelines Program Plan for 2004/2005 follows.

- I. General Information
- II. Legal Authority
- III. What Are Effluent Guidelines?
- IV. What Requirements Apply to This Effluent Guidelines Program Plan Effort?
- V. What Is the Purpose of Today's **Federal Register** Notice?
- VI. 2003 Annual Review of Effluent Guidelines That EPA Has Promulgated Under CWA Section 304(b)
- VII. What Will Be the Focus of EPA's 2004 Annual Review?
- VIII. Identification of and Schedule for Possible Categories for Potential New Effluent Guidelines
- IX. Request for Comment and Information

#### I. General Information

##### A. Regulated Entities

Today's preliminary Effluent Guidelines Program Plan for 2004/2005 does not contain regulatory requirements, nor will the final plan do so. Rather, today's preliminary Effluent Guidelines Program Plan describes the current status of the effluent guidelines planning process, presents the results of the Agency's annual review of the effluent guidelines EPA has already promulgated for industrial categories, and identifies industrial categories that EPA expects to investigate further for the possible development or revision of effluent limitations guidelines.

##### B. How Can I Get Copies of This Document and Other Related Information?

###### 1. Docket

EPA has established an official public docket for this action under Docket ID No. OW-2003-0074. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include information claimed as Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that