

#### D. Labeling Issues

1. There are many differences between the labeling requirements required by FDA's OTC drug labeling requirements and EPA's pesticide labeling requirements. For example, the formats and the order in which information is presented are quite different. FDA allows the use of the word "warning" on labels; however it is only allowed as an indicator of toxicity level on pesticide labels. Various required section headings are different. Please comment on how such labeling differences can be reconciled.

2. FDA ingredient statements list the "inactive or inert" ingredients more often and in greater detail than do EPA approved labels. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not require the listing of the identities of inert ingredients on the label. Are there ways to provide the insect repellent inert ingredients information in the product's labeling to satisfy the drug requirements of the FFDCA?

3. Is it desirable for users of these products to have a single integrated label, or would an insect repellent (EPA) and a sunscreen (FDA) section in the product's labeling be preferable?

4. Should the insect repellent/sunscreen combination products be required to have a statement on the front panel of the label specifically identifying the product as containing an insect repellent (such as, This Product Contains An Insect Repellent)? Would this be useful to help consumers distinguish between sunscreen products that contain pesticides from the typical sunscreen drug products that contain no pesticides?

#### List of Subjects

Environmental protection, Administrative practice and procedure, Intergovernmental relations, Pesticides, Pests.

Dated: February 13, 2007.

**James B. Gulliford,**

*Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*

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#### ENVIRONMENTAL PROTECTION AGENCY

[Docket# EPA-RO4-SFUND-2007-0129; FRL-8279-3]

#### Starmet CMI; Barnwell, Barnwell County, SC; Notice of Settlement

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Notice of settlement.

**SUMMARY:** Under Section 122(g) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into a settlement for reimbursement of past response costs with the Alaron Corporation concerning the Starmet CMI Superfund Site located in Barnwell, Barnwell County, South Carolina.

**DATES:** The Agency will consider public comments on the settlement until March 26, 2007. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

**ADDRESSES:** Copies of the settlement are available from Ms. Paula V. Batchelor. Submit your comments, identified by Docket ID No. EPA-RO4-SFUND-2007-0129 or Site name Starmet CMI Superfund Site by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.

- *E-mail:* [Batchelor.Paula@epa.gov](mailto:Batchelor.Paula@epa.gov)

- *Fax:* 404/562-8842/Attn Paula V. Batchelor

*Mail:* Ms. Paula V. Batchelor, U.S. EPA Region 4, WMD-SEIMB, 61 Forsyth Street, SW., Atlanta, Georgia 30303. "In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503."

*Instructions:* Direct your comments to Docket ID No. EPA-RO4-SFUND-2007-0129. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at

*www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-

mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>

*Docket:* All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the U.S. EPA Region 4 office located at 61 Forsyth Street, SW., Atlanta, Georgia 30303. Regional office is open from 7 a.m. until 6:30 p.m.. Monday through Friday, excluding legal holidays.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** Paula V. Batchelor at 404/562-8887.

Dated: February 7, 2007.

**Rosalind H. Brown,**

*Chief, Superfund Enforcement & Information Management Branch, Superfund Division.*

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#### ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2003-0079; FRL-OW-8280-2]

#### Aquatic Life Ambient Freshwater Quality Criteria—Copper 2007 Revision

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Notice of Availability.

**SUMMARY:** The Environmental Protection Agency (EPA) announces the availability of the 2007 revised recommended aquatic life ambient freshwater quality criteria for copper. The Clean Water Act (CWA) requires

EPA to develop and publish, and from time to time revise, criteria for water accurately reflecting the latest scientific knowledge. These criteria provide EPA's recommendations to states and authorized tribes as they establish their water quality standards as state or tribal law or regulation. An EPA water quality criterion does not substitute for requirements of the CWA or EPA regulations, nor is an EPA criteria recommendation a regulation. It does not impose legally binding requirements on the EPA, states, authorized tribes or the regulated community. State and tribal decision makers have discretion to adopt approaches that differ from EPA's water quality criteria recommendations on a case-by-case basis. Today, the Agency is making a revised recommendation about water quality criteria for copper.

**ADDRESSES:** Copies of the criteria document entitled, Aquatic Life Ambient Freshwater Quality Criteria—Copper 2007 Revision (EPA-822-R-07-001) may be obtained from EPA's Water Resource Center by phone at (202) 566-1729, or by e-mail to [center.water.resource@epa.gov](mailto:center.water.resource@epa.gov) or by conventional mail to: U.S. EPA Water Resource Center, 4101T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. You can also download the criteria document and the fact sheet from EPA's Web site at <http://www.epa.gov/waterscience/criteria/copper/index.htm>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Luis Cruz, Health and Ecological Criteria Division (4304T), U.S. EPA, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; (202) 566-1095; [cruz.luis@epa.gov](mailto:cruz.luis@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Interested Entities*

Entities potentially interested in today's notice are those that produce, use, or regulate copper. Categories and entities interested in today's notice include:

| Category   | Examples of interested entities  |
|--|--|
| State/Local/Tribal Government.<br>Industry ..... | States, Tribes and Municipalities.<br>Mining, fabricated metal products, electric equipment, leather products. |

This table is not exhaustive, but rather provides a guide for readers regarding the entities likely to 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 This Document and Other Related Information?*

1. Docket

EPA established an official public docket for the initial draft criteria document and scientific views received under Docket ID No. EPA-HQ-OW-2003-0079. The official public docket will also consist of the 2007 revised criteria document and scientific views received. 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. Publicly available docket materials are available either electronically through <http://www.regulations.gov>, or in hard copy 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 Water Docket is (202) 566-2426. To view these documents and materials, please call ahead to schedule an appointment. Every user is entitled to copy 266 pages per day before incurring a charge. The Docket may charge 15 cents a page for each page over the 266-page limit plus an administrative fee of \$25.00.

2. Electronic Access

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

**II. Background and Today's Notice of Availability**

*A. What Are EPA Recommended Ambient Water Quality Criteria?*

An EPA recommended ambient water quality criterion is a description of the amount of a pollutant or other measurable substance in water that, when met, will protect aquatic life and/or human health. Water quality criteria are based on the factors specified in section 304(a) of the Clean Water Act, including the kind and extent of effects of the pollutant on human health and aquatic organisms. Section 304(a) of the Clean Water Act (CWA or the Act) requires EPA to develop and publish and, from time to time, revise, recommended ambient water quality criteria to accurately reflect the latest scientific knowledge. An EPA water criterion does not substitute for

requirements of the CWA or EPA regulations, nor is an EPA criteria recommendation a regulation. It does not impose legally binding requirements on EPA, states, authorized tribes or the regulated community. State and tribal decision makers have discretion to adopt approaches that differ from EPA's water quality criteria recommendations on a case-by-case basis.

Ambient water quality criteria developed under section 304(a) provide guidance to states and tribes in adopting water quality criteria into their water quality standards under section 303(c) of the CWA. Once adopted by a state or tribe, the water quality standards are then a basis for developing regulatory controls on the discharge or release of pollutants and other alterations of water quality. EPA's section 304(a) criteria also provide a scientific basis for EPA to develop any necessary federal water quality regulations under section 303(c) of the CWA.

*B. What Is the Relationship Between the Water Quality Criteria and Your State or Tribal Water Quality Standards?*

The revised recommended criteria in today's notice are based on the factors specified in section 304(a) of the Clean Water Act, including the kind and extent of effects of the pollutant on human health and aquatic organisms. EPA's recommended criteria are used by the states and tribes in developing their regulatory criteria under section 303(c) of the CWA. Under the Clean Water Act, regulatory water quality criteria must protect the designated use, independent of the economic and technical feasibility of meeting the criteria. Economic and technical feasibility factors are considered by states and tribes when they adopt designated uses into their water quality standards under section 303(c) of the Act and when states, tribes, and EPA consider variance requests. Moreover, states and tribes may also consider alternative scientifically defensible approaches to adopting criteria into their water quality standards.

Section 303(c)(1) of the CWA requires states and authorized tribes to review and modify, if appropriate, their water quality standards at least once every three years. Water quality standards consist of designated uses, water quality criteria to protect those uses, a policy for antidegradation, and general policies for application and implementation. States and authorized tribes must adopt water quality criteria that protect designated uses. Protective criteria, based on a sound scientific rationale, contain appropriate factors to protect the designated uses. Criteria may be

either narrative or numeric. States and authorized tribes have four options when adopting water quality criteria for parameters for which EPA has published section 304(a) criteria. They may: (1) Establish numerical values based on recommended CWA section 304(a) criteria; (2) Establish numerical values based on CWA section 304(a) criteria modified to reflect site-specific conditions; (3) Establish numerical values based on other scientifically defensible methods; or (4) Establish narrative criteria or criteria based upon biomonitoring methods where numerical criteria cannot be determined or to supplement numerical criteria. See 40 CFR 131.11(b).

Pursuant to 40 CFR 131.21, water quality criteria that states and authorized tribes adopted and submitted to EPA before May 30, 2000, are in effect for CWA purposes. The criteria remain in effect unless and until EPA promulgates federal regulations that supersede them or EPA approves a revised state criteria. See, e.g., the National Toxics Rule, 40 CFR 131.36; Water Quality Standards for Idaho, 40 CFR 131.33. New or revised water quality criteria that states and authorized tribes adopted into law or regulation and submit to EPA on or after May 30, 2000, are in effect for CWA purposes only after EPA approves them.

#### *C. What Is the History of Today's Revised Criteria?*

EPA notified the public of its intentions to revise the recommended aquatic life criteria for copper in the **Federal Register** on October 29, 1999 (63 FR 58406). On December 31, 2003 EPA published a Federal Register Notice announcing the availability of the document Notice of Availability of Draft Aquatic Life Criteria Document for Copper and Request for Scientific Views (68 FR 75552). The initial draft criteria document contained recommendations for both freshwater and saltwater criteria derivations; however, EPA has since determined that the biotic ligand model requires further development before it is suitable for use to evaluate saltwater data. On March 9, 2004 EPA published a Federal Register Notice (69 FR 11012) announcing the reopening of the period to submit scientific views in response to requests from the public. Comments received were supportive of using the BLM for deriving freshwater criteria for copper. Issues related to criteria derivation process were answered, as well as corrections in matters of scientific relevance related to the applicability of the BLM.

#### *D. What Is Copper?*

Copper is an abundant trace element found in the earth's crust and is a naturally occurring element that is generally present in surface waters. Copper is a micronutrient at low concentrations and recognized as essential to virtually all plants and animals. Historically, elevated levels of copper have been linked to adverse effects on aquatic organisms and concerns have prompted its inclusion as a priority pollutant. Currently, there are 629 rivers and streams listed as impaired for copper and 5 for contaminated sediments due to copper.

#### *E. What Is New About the Revised Criteria?*

The aquatic life criteria document titled, "Aquatic Life Ambient Freshwater Quality Criteria—Copper 2007 Revision" (EPA-822-R-07-001), contains revised recommendations for freshwater aquatic life criteria for copper. These revised criteria recommendations are based in part on new data that have become available since EPA's last comprehensive criteria updates for copper, "Ambient Water Quality Criteria for Copper—1984" (EPA-440/5-84-031). EPA derived the freshwater criteria recommendations presented in this draft document based on the principles set forth in EPA's 1985 Guidelines for Deriving Numerical National Aquatic Life Criteria for Protection of Aquatic Organisms and Their Uses. In addition to incorporating new data, the freshwater criterion maximum concentration (CMC or "acute criterion") also relies on a new scientific model, the biotic ligand model (BLM), in the criteria derivation procedures. The freshwater criterion continuous concentration (CCC or "chronic criterion") is based on a BLM derived acute value divided by a final acute-chronic ratio. Where used, the application of the BLM will replace the need for site-specific modifications, such as Water Effect Ratio, to account for site-specific chemistry influences on metal toxicity.

#### *F. How Do BLM-Derived Criteria Differ From Hardness-Dependent Criteria?*

The biotic ligand model is a metal bioavailability model based on recent information about the chemical behavior and physiological effects of metals in aquatic environments. Earlier freshwater aquatic life criteria for copper published by the Agency were based on empirical relationships of toxicity to water hardness. That is, a relationship was established linking the criteria concentrations with water

hardness. These hardness-dependent criteria, however, represented combined effects of different water quality variables (such as pH and alkalinity) correlated with hardness. Unlike the empirically derived hardness-dependent criteria, the BLM explicitly accounts for individual water quality variables and addresses variables that EPA had not previously factored into the hardness relationship. Where the previous freshwater aquatic life criteria were hardness-dependent, these revised criteria are dependent on a number of water quality parameters (e.g., calcium, magnesium, dissolved organic carbon) described in the document. BLM-based criteria can be more stringent than the current hardness-based copper criteria and in certain cases the current hardness-based copper criteria may be overly stringent for particular water bodies.

More information on the development and application of the biotic ligand model is available in the criteria document as well as in The Biotic Ligand Model: Technical Support Document for Its Application to the Evaluation of Water Quality Criteria for Copper (EPA 822-R-03-027) and Integrated Approach to Assessing the Bioavailability and Toxicity of Metals in Surface Waters and Sediments (EPA-822-E-99-001).

#### *G. What Are the New Revised Criteria for Copper?*

The available toxicity data, when evaluated using the procedures described in the "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" indicate that freshwater aquatic life should be protected if the 24-hour average and four-day average concentrations do not respectively exceed the acute and chronic criteria concentrations calculated by the Biotic Ligand Model.

A return interval of 3 years between exceedances of the criterion continues to be EPA's general recommendation. However, the resilience of ecosystems and their ability to recover differ greatly. Therefore, scientific derivation of alternative frequencies for exceeding criteria may be appropriate.

Dated: February 15, 2007.

**Ephraim King,**

*Director, Office of Science and Technology.*  
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