

the control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum* and for the control of mortality in freshwater-reared *Oncorhynchus mykiss* due to columnaris disease associated with *Flavobacterium columnare*. The supplemental NADA is approved as of July 6, 2008, and the regulations are amended in 21 CFR 558.450 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2(c)), this supplemental approval qualifies for 7

years of exclusive marketing rights beginning on the date of approval because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

■ 2. In § 558.450, in the table in paragraph (d)(5)(v), in the "Limitations" column, remove "; do not administer when water temperature is below 9 °C (48.2 °F)"; redesignate paragraph (d)(5)(vi) as paragraph (d)(5)(vii); and add new paragraph (d)(5)(vi) to read as follows:

#### § 558.450 Oxytetracycline.

\* \* \* \* \*

(d) \* \* \*

(5) \* \* \*

| Oxytetracycline amount         | Indications for use                                                                                                                                                                                                                                                                               | Limitations                                                                                                                                                                                                                                                                                              | Sponsor          |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| *                              | *                                                                                                                                                                                                                                                                                                 | *                                                                                                                                                                                                                                                                                                        | *                |
| (vi) 3.75 g/100 lb of fish/day | 1. Freshwater-reared salmonids: For control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> .<br>2. Freshwater-reared <i>Oncorhynchus mykiss</i> : For control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i> . | Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed.<br>Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed. | 066104<br>066104 |
| *                              | *                                                                                                                                                                                                                                                                                                 | *                                                                                                                                                                                                                                                                                                        | *                |

Dated: July 28, 2008.

**Bernadette Dunham,**

Director, Center for Veterinary Medicine.

[FR Doc. E8-18129 Filed 8-6-08; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2008-0470]

RIN 1625-AA11

#### Regulated Navigation Area and Safety Zone, Chicago Sanitary and Ship Canal, Romeoville, IL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is revising the dates and is reinstating a temporary

regulated navigation area and safety zone on the Chicago Sanitary and Ship Canal near Romeoville, IL. This regulated navigation area and safety zone places navigational and operational restrictions on all vessels transiting through the electrical dispersal barrier IIA.

**DATES:** This rule is effective from September 03, 2008 to October 15, 2008.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2008-0470 and are available online at [www.regulations.gov](http://www.regulations.gov). They are also available for inspection or copying at two locations: The Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the U.S. Coast Guard Sector Lake Michigan, 2420 South Lincoln Memorial

Drive, Milwaukee, Wisconsin 53207, between 8:30 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions regarding this rule call CDR Tim Cummins, Deputy Prevention Division, Ninth Coast Guard District, telephone 216-902-6045. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory Information

On July 2, 2008 we published a Temporary Final Rule (73 FR 37810). This Temporary Final Rule revises dates and reinstates the Temporary Final Rule published on July 2, 2008.

Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. This regulated navigation area and safety zone is being implemented to ensure continued safe

navigation of commercial and recreational traffic. Accordingly, it requires immediate activation. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety of persons and vessels and immediate action is necessary to prevent possible loss of life or property.

### Background and Purpose

The electrodes on the demonstration electrical dispersal barrier 1 located between Mile Markers 296.1 and 296.7 of the Chicago Sanitary and Ship Canal are beginning to fail. This barrier was constructed to prevent Asian Carp from entering Lake Michigan through the Illinois River system by generating a low-voltage electric field across the canal. The Army Corps of Engineers intends to shutdown barrier 1 and begin the process of replacing the barrier electrodes which run across the bottom of the canal. Divers will be in the water and a barge-mounted crane will be operating during maintenance operations to barrier 1. Electrical dispersal barrier IIA located on the Chicago Sanitary and Ship Canal 270 feet south of Mile Marker 296.1 to Mile Marker 296.7 will be in operation while repairs are being made to demonstration electrical dispersal barrier 1. Barrier IIA will operate continuously for a two week period before taking barrier 1 off line for electrode replacement. Electrical dispersal barrier IIA generates a more powerful electric field than barrier 1 over a larger area within the Chicago Sanitary and Ship Canal.

The Coast Guard and U.S. Army Corps of Engineers conducted field tests to ensure the continued safe navigation of commercial and recreational traffic across the barrier; however, results indicated an arcing risk and hazardous electrical discharges as vessels transited the barrier posing a serious risk to navigation through the barrier. To mitigate these risks, navigational and operational restrictions will be placed on all vessels transiting through the vicinity. Until the potential electrical hazards can be rectified, the Coast Guard will require vessels transiting the regulated navigation area to adhere to specified operational and navigational requirements. This regulation will be 43 days in length to provide enough time for maintenance to be performed to the barrier. This type of maintenance has never been performed on Barrier I and therefore, an extended amount of time was requested in the event it is needed.

### Discussion of Rule

This rule will suspend 33 CFR 165.923 and place additional restrictions on all vessels transiting through electrical dispersal barrier IIA located on the Chicago Sanitary and Ship Canal from September 03, 2008 until October 15, 2008. The regulated navigation area encompasses all waters of the Chicago Sanitary and Ship Canal 270 feet south of the Romeo Road Bridge Mile Marker 296.1 to the south side of the Aerial Pipeline Mile Marker 296.7. The requirements placed on all vessels include: All up-bound and down-bound barge tows that contain one or more Red Flag barges transiting through the restricted navigation area must be assisted by a bow boat at least one mile above the restricted navigation area to at least one mile below the restricted navigation area. Red Flag barges are barges containing hazardous materials as identified by Commodity Codes:

- 01 (Empty with previous hazardous material)
- 20 (Petroleum and Petroleum Products)
- 21 (Crude Petroleum)
- 22 (Gasoline, Jet Fuel and Kerosene)
- 23 (Distillate, Residual and other Fuel Oils; Lubricating Oils and Greases)
- 24 (Petroleum Pitches, Coke Asphalt, Naphtha and Solvents)
- 30 (Chemicals and Related Products)
- 31 (Fertilizer-Nitrogenous, Potassic, Phosphatic and Others)
- 32 (Organic Industrial Chemicals {Crude Products} from Coal, Tar, Petroleum and Natural Gas, Dyes, Organic Pigment Dyeing and Tanning Materials, Alcohols, Benzene; Inorganic Industrial Chemicals {Sodium Hydroxide}; Radioactive and Associated Materials; Drugs)

The U.S. Army Corps of Engineers will contract bow boat assistance for barge tows containing one or more Red Flag barges. Information on how to contact the contractor for bow boat assistance will be provided to the public in a Broadcast Notice to Mariners. Towing assistance will be provided from at least one mile above the restricted navigation area to at least one mile below the restricted navigation area.

This rule prohibits all vessels from loitering in the regulated navigation area. Vessels may enter the regulated navigation area for the sole purpose of transiting to the other side and must maintain headway throughout the transit. The rule also requires all personnel on open decks to wear a Coast Guard approved Type I personal flotation device while in the regulated navigation area. In addition, vessels may

not moor or lay up on the right or left descending banks in the regulated navigation area; towboats may not make or break tows in the regulated navigation area; vessels may not pass (meet or overtake) in the regulated navigation area. All vessels must make a SECURITE call when approaching the barrier to announce intentions and work out passing arrangements on either side. Finally, commercial tows transiting the regulated navigation area must be made up with wire rope to ensure electrical connectivity between all segments of the tow.

These restrictions are necessary for safe navigation of the regulated navigation area and to ensure the safety of vessels and their personnel as well as the public's safety due to the electrical discharges noted during safety tests conducted by the U.S. Army Corps of Engineers. Deviation from this rule is prohibited unless specifically authorized by the Commander, Ninth Coast Guard District or his designated representative. The Commander, Ninth Coast Guard District will designate Captain of the Port Lake Michigan as his designated representative for the purposes of this rule.

A temporary safety zone will be in place while repairs are being made to barrier 1. This temporary safety zone is necessary to ensure the safety of workers and vessels during maintenance operations to barrier 1 on the Chicago and Sanitary Ship Canal.

The maintenance on barrier 1 will occur between 7 a.m., September 15, 2008 and 5 p.m., October 15, 2008. The safety zone will be enforced from 7 a.m. to 12 p.m. and 1 p.m. to 5 p.m. on September 15, 2008 through October 15, 2008. The safety zone will encompass all waters of the Chicago Sanitary Ship Canal from mile marker 296.1 to mile marker 296.7.

The Captain of the Port will cause notice of enforcement of the safety zone established by this section to be made by all appropriate means to the affected segments of the public. Such means of notification will include, but is not limited to, Broadcast Notice to Mariners and Local Notice to Mariners. The Captain of the Port will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone is terminated.

### Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

## Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This determination is based on the fact that traffic will still be able to transit through the regulated navigation area and the minimal time that vessels will be restricted from the safety zone. The safety zone is an area where the Coast Guard expects insignificant adverse impact to mariners from the zones' activation.

## Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

This rule would affect the following entities, some of which might be small: The owners and operators of vessels intending to transit or anchor in a portion of the Chicago Sanitary Ship Canal from September 03, 2008 to October 15, 2008.

This regulated navigation area and safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. Vessel traffic will be able to transit through the regulated navigation area. The U.S. Army Corps of Engineers will contract bow boat assistance for barge tows containing one or more Red Flag barges. Vessel traffic will only be limited for one five hour period and one four hour period each day the safety zone is in effect. In the event this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port Lake Michigan to transit through the safety zone. The Coast Guard will give notice to the public via a Broadcast Notice to Mariners that the regulation is in effect.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity

and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

## Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact CDR Tim Cummins, Deputy Prevention Division, Ninth Coast Guard District, 1240 East Ninth Street, Cleveland, OH 44199; 216–902–6049. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

## Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

## Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

## Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

## Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

## Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

## Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

## Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined that these regulations and fishing rights protection need not be incompatible. We have also determined that this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Nevertheless, Indian Tribes that have questions concerning the provisions of this rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

## Energy Effects

We have analyzed this rule under Executive order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

## Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency

provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedure; and related management system practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### Environment

We have analyzed this rule under Commandant Instruction M16475.ID and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C.4321–4370f), and have made a preliminary determination, under the Instruction, that this action is not likely to have a significant effect on the human environment. A preliminary “Environmental Analysis Check List” supporting this preliminary determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

#### § 165.923 [Suspended]

■ 2. Section 165.923 is suspended from September 03, 2008 until October 15, 2008.

■ 3. A new temporary section 165.T09–4002 is added as follows:

#### § 165.T09–4002 Temporary Regulated Navigation Area, Chicago Sanitary and Ship Canal, Romeoville, IL.

(a) *Regulated Navigation Area.* The following is a Regulated Navigation Area: All waters of the Chicago Sanitary and Ship Canal, Romeoville, IL, 270 feet south of the Romeo Road Bridge Mile Marker 296.1 to the south side of the Aerial Pipeline Mile Marker 296.7.

(b) *Effective period.* This section is effective from September 03, 2008 until October 15, 2008.

(c) *Definitions.* The following definitions apply to this section: *Designated representative* means the Captain of the Port Lake Michigan.

*Red Flag barges* means barges containing hazardous materials as identified by the following Commodity Codes:

- (1) 01 (Empty with previous hazardous material);
- (2) 20 (Petroleum and Petroleum Products);
- (3) 21 (Crude Petroleum);
- (4) 22 (Gasoline, Jet Fuel and Kerosene);
- (5) 23 (Distillate, Residual and other Fuel Oils; Lubricating Oils and Greases);
- (6) 24 (Petroleum Pitches, Coke Asphalt, Naphtha and Solvents);
- (7) 30 (Chemicals and Related Products);
- (8) 31 (Fertilizer-Nitrogenous, Potassic, Phosphatic and Others); and
- (9) 32 (Organic Industrial Chemicals {Crude Products} from Coal, Tar, Petroleum and Natural Gas, Dyes, Organic Pigment Dying and Tanning Materials, Alcohols, Benzene; Inorganic Industrial Chemicals {Sodium Hydroxide}; Radioactive and Associated Materials; Drugs)

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.13 apply.

(2) All up-bound and down-bound barge tows that contain one or more Red Flag barges transiting through the restricted navigation area must be assisted by a bow boat until the entire tow is clear of the expanded restricted navigation area boundaries.

(i) Information on how to contact the contractor for bow boat assistance will be provided to the public in a Broadcast Notice to Mariners.

(ii) Towing assistance will be provided from at least one mile above the restricted navigation area to as least one mile below the restricted navigation area.

(3) All vessels are prohibited from loitering in the regulated navigation area.

(4) Vessels may enter the regulated navigation area for the sole purpose of transiting to the other side, and must

maintain headway throughout the transit.

(5) All personnel on open decks must wear a Coast Guard approved Type I personal flotation device while in the regulated navigation area.

(6) Vessels may not moor or lay up on the right or left descending banks of the regulated navigation area.

(7) Towboats may not make or break tows in the regulated navigation area.

(8) Vessels may not pass (meet or overtake) in the regulated navigation area and must make a SECURITE call when approaching the barrier to announce intentions and work out passing arrangements on either side.

(9) Commercial tows transiting the regulated navigation area must be made up with wire rope to ensure electrical connectivity between all segments of the tow.

(e) *Compliance.* All persons and vessels must comply with this section and any additional instructions of the Ninth Coast Guard District Commander, or his designated representative.

■ 4. A new temporary section 165.T09–4003 is added as follows:

#### § 165.T09–4003 Safety Zone; Chicago Sanitary and Ship Canal, Romeoville, IL.

(a) *Safety Zone.* The following area is a temporary safety zone: All waters of the Chicago Sanitary and Ship Canal from mile marker 296.1 to 296.7.

(b) *Effective period.* This regulation is effective from 7 a.m., September 15, 2008, to 5 p.m., October 15, 2008. The safety zone will be enforced from 7 a.m. to 12 p.m. and 1 p.m. to 5 p.m. on September 15, 2008, through October 15, 2008.

(c) *Regulations.* (1) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan, or his on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Lake Michigan or his on-scene representative.

(3) The “on-scene representative” of the Captain of the Port is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his on-scene representative may be contacted via VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Lake

Michigan or his on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Lake Michigan or his on-scene representative.

Dated: July 29, 2008.

**Peter V. Neffenger,**

*Rear Admiral, U.S. Coast Guard Commander,  
Ninth Coast Guard District.*

[FR Doc. E8-18078 Filed 8-6-08; 8:45 am]

BILLING CODE 4910-15-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R08-OAR-2007-1030; FRL-8573-5]

#### Approval and Promulgation of Air Quality Implementation Plans; Colorado; Affirmative Defense Provisions for Malfunctions; Common Provisions Regulation

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

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action approving a State Implementation Plan (SIP) revision submitted by the State of Colorado on August 1, 2007. This revision establishes affirmative defense provisions for source owners and operators for excess emissions during periods of malfunction. The affirmative defense provisions are contained in the State of Colorado's Common Provisions regulation. The intended effect of this action is to approve only those portions of Colorado's Common Provisions regulation submitted on August 1, 2007 that relate to the affirmative defense for malfunctions. This action is being taken under section 110 of the Clean Air Act. **DATES:** This rule is effective on October 6, 2008, without further notice, unless EPA receives adverse comment by September 8, 2008. If adverse comment is received, EPA will publish a timely withdrawal of this direct final rule in the **Federal Register** informing the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R08-OAR-2007-1030, by one of the following methods:

- <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- E-mail: [videtich.callie@epa.gov](mailto:videtich.callie@epa.gov) and [komp.mark@epa.gov](mailto:komp.mark@epa.gov).
- Fax: (303) 312-6064 (please alert the individual listed in the **FOR FURTHER**

**INFORMATION CONTACT** section if you are faxing comments).

- **Mail:** Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P-A, 1595 Wynkoop Street, Denver, Colorado 80202-1129.

- **Hand Delivery:** Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P-A, 1595 Wynkoop Street, Denver, Colorado 80202-1129. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. EPA-R08-OAR-2007-1030. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://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 <http://www.regulations.gov> or e-mail. The <http://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 <http://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 instructions on submitting comments, go to section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** All documents in the docket are listed in the <http://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 <http://www.regulations.gov> or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202-1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Mark Komp, Air Program, 1595 Wynkoop Street, Mailcode: 8P-A, Denver, Colorado 80202-1129, (303) 312-6022, [komp.mark@epa.gov](mailto:komp.mark@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

- I. General Information
- II. Background of State Submittal
- III. EPA Analysis of State Submittal
- IV. Consideration of Section 110 (l) of the CAA
- V. Final Action
- VI. Statutory and Executive Order Reviews

##### Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

- (i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.
- (ii) The words *EPA*, *we*, *us* or *our* mean or refer to the United States Environmental Protection Agency.
- (iii) The initials *SIP* mean or refer to State Implementation Plan.
- (iv) The words *State* or *Colorado* mean the State of Colorado unless the context indicates otherwise.

##### I. General Information

###### A. What Should I Consider as I Prepare My Comments for EPA?

1. **Submitting CBI.** Do not submit this information to EPA through <http://www.regulations.gov> or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked