

FOR FURTHER INFORMATION CONTACT:

Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200.

SUPPLEMENTARY INFORMATION:

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, FDA has published the proposed rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (“the produce safety rule” or “the proposed rule”) to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). FDA has proposed these standards as part of our implementation of the FDA Food Safety Modernization Act (FSMA). These standards would not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance would be eligible for exemption from the requirements of this rule. The proposed rule would set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. We expect that the proposed rule, if finalized as proposed, would reduce foodborne illness associated with the consumption of contaminated produce.

For the proposed rule, the Agency relied on a categorical exclusion from the need to prepare an Environmental Assessment or EIS under 21 CFR 25.30(j). Based on currently available information, including comments received, and upon further analysis, FDA has determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)) and, therefore, an EIS is necessary for the final rule. For example, switching from surface to ground water was originally considered a cost- and time-prohibitive option that was unlikely to occur to any significant extent given that monitoring data available prior to the publication of the proposed rule showed that *Escherichia coli* exceedance of the proposed

standard occurred during 5 percent of the monitoring period with 55 percent of the incidents being no more than 2 days, as discussed in the categorical exclusion memo (see Ref. 266 of the proposed rule). Public comment, subsequent to the publication of the proposed rule, has indicated that in some regions current irrigation practices use water that is unlikely to meet the proposed microbial standards for much, if not all of the growing season. Consequently, if such standards are finalized, ground water is likely to be explored as a more viable alternative water source for irrigation in these regions than previous information had indicated. Given recently highlighted concerns of ground water depletion (Ref. 1), FDA has determined that the use of ground water for irrigation, in response to a microbial standard, may significantly affect the quality of the human environment. Similarly, comments received caused FDA to reevaluate the proposed requirements for biological soil amendments of animal origin, which propose an increasingly stringent set of application restrictions based on the likelihood of the soil amendment harboring pathogens. These proposed requirements, if finalized, are expected to result in changes in current use of treated and untreated biological soil amendments of animal origin or potentially greater use of synthetic fertilizers. Changes in the type or handling of soil amendments may significantly affect the quality of the human environment.

The purpose of the public scoping process for the EIS is to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives, and the extent to which those issues and impacts will be analyzed in the EIS. The EIS will be prepared in accordance with section 102(2)(C) of NEPA (Pub. L. 91-190), FDA’s NEPA implementing regulations (21 CFR Part 25), and the CEQ regulations for implementing NEPA (40 CFR Parts 1500-1508). Federal, State, and local Agencies, along with tribes and other stakeholders that may be interested in or affected by the produce safety rule are invited to participate in the scoping process. Some Federal Agencies may request or be requested by the FDA to participate in the development of the environmental analysis as a cooperating agency. FDA has previously sought comment on potential environmental effects as part of the public comment period for the proposed rule, including specific questions regarding agricultural water,

biological soil amendments of animal origin, and wildlife (78 FR 3504 at 3616, 3619-3620). FDA believes that these questions are still relevant to the environmental analysis and will consider comments received. FDA encourages additional comments, as part of this scoping process, on what specific issues, alternatives, mitigation measures, or other information FDA should include for further analysis in the EIS for the produce safety rule.

References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. U.S. Geological Survey. 2013. Groundwater Depletion in the United States (1900-2008). Scientific Investigation Report 2013-5079. Available at: <http://pubs.usgs.gov/sir/2013/5079/SIR2013-5079.pdf>. Accessed July 30, 2013.

Dated: August 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF DEFENSE**Office of the Secretary****32 CFR Part 199**

[DOD-2011-HA-0136]

RIN 0720-AB56

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE Uniform Health Maintenance Organization (HMO) Benefit—Prime Enrollment Fee Exemption for Survivors of Active Duty Deceased Sponsors and Medically Retired Uniformed Services Members and Their Dependents; Withdrawal

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule; withdrawal.

SUMMARY: On Thursday, August 8, 2013 (78 FR 48366-48367), the Department of Defense published a proposed rule titled “Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE Uniform Health Maintenance Organization (HMO) Benefit—Prime Enrollment Fee Exemption for Survivors of Active Duty Deceased Sponsors and Medically Retired Uniformed Services

Members and Their Dependents.” Subsequent to the publication of the proposed rule in the **Federal Register**, DoD discovered that an identical proposed rule published in the **Federal Register** on Friday, June 7, 2013 (78 FR 34292–34293). DoD is hereby withdrawing the proposed rule that published in the **Federal Register** on Thursday, August 8, 2013.

DATES: As of August 19, 2013 the proposed rule published August 8, 2013 (78 FR 48366–48367), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, 571–372–0485.

Dated: August 14, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–20121 Filed 8–16–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2011–0888; EPA–R05–OAR–2011–0969; EPA–R05–OAR–2012–0567; EPA–R05–OAR–2012–0988; FRL–9900–19–Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Infrastructure SIP Requirements for the 2008 Lead and Ozone National Ambient Air Quality Standards; Indiana PSD; Indiana State Board Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve elements of state implementation plan (SIP) submissions by Indiana regarding the infrastructure requirements of sections 110(a)(1) and (2) of the Clean Air Act (CAA) for the 2008 lead and 2008 8-hour ground level ozone national ambient air quality standards (2008 Pb and ozone NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state’s air quality management program are adequate to meet the state’s responsibilities under the CAA. EPA is also proposing to approve portions of submissions from Indiana addressing EPA’s requirements for the prevention of significant deterioration (PSD) program. Lastly, EPA is proposing to approve a submission from Indiana addressing the state board requirements under section 128 of the CAA.

DATES: Comments must be received on or before September 18, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2011–0888 (2008 Pb infrastructure SIP elements), EPA–R05–OAR–2011–0969 (2008 ozone infrastructure SIP elements), EPA–R05–OAR–2012–0567 (PSD elements), or EPA–R05–OAR–2012–0988 (state board requirements), by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *Email*: aburano.douglas@epa.gov.

3. *Fax*: (312) 408–2279.

4. *Mail*: Douglas Aburano, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery*: Douglas Aburano, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID. EPA–R05–OAR–2011–0888 (2008 Pb infrastructure SIP elements), EPA–R05–OAR–2011–0969 (2008 ozone infrastructure SIP elements), EPA–R05–OAR–2012–0567 (PSD elements), or EPA–R05–OAR–2012–0988 (state board requirements). 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 email. 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 email comment directly to EPA without going through *www.regulations.gov* your email 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.

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. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Andy Chang, Environmental Engineer, at (312) 886–0258 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Andy Chang, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0258, chang.andy@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA. This supplementary information section is arranged as follows:

- I. What should I consider as I prepare my comments for EPA?
- II. What is the background of these SIP submissions?
 - A. What state SIP submissions does this rulemaking address?
 - B. Why did the state make these SIP submissions?
 - C. What is the scope of this rulemaking?
- III. What guidance is EPA using to evaluate these SIP submissions?
- IV. What is the result of EPA’s review of these SIP submissions?
 - A. Section 110(a)(2)(A)—Emission Limits and Other Control Measures
 - B. Section 110(a)(2)(B)—Ambient Air Quality Monitoring/Data System
 - C. Section 110(a)(2)(C)—Program for Enforcement of Control Measures; PSD
 - D. Section 110(a)(2)(D)—Interstate Transport
 - E. Section 110(a)(2)(E)—Adequate Resources
 - F. Section 110(a)(2)(F)—Stationary Source Monitoring System