ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Connecticut on November 19, 2012. We propose to approve Connecticut’s request to remove two regulations from its SIP that regulate “open burning” and “portable fuel container spillage control.” In place of the open burning regulation, we propose to approve into the Connecticut SIP a Connecticut statute that controls open burning. We also propose to approve a definition of “brush,” which was included in a December 15, 2015 SIP submittal by Connecticut to meet infrastructure requirements of the Clean Air Act for the 2012 fine particle (PM2.5) National Ambient Air Quality Standards (NAAQS). The requirements in the Connecticut portable fuel container regulation have been superseded by federal portable fuel container requirements. This action is being taken in accordance with the Clean Air Act.

DATES: Written comments must be received on or before October 3, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2015–0471 by one of the following methods:


2. Email: arnold.anne@epa.gov.


4. Hand Delivery or Courier. Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEPP–2), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office’s normal hours of operation. The Regional Office’s official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

Please see the direct final rule which is located in the Rules Section of this Federal Register for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEPP–2), Boston, MA 02109–3912, telephone number (617) 918–1684, fax number (617) 918–0684, email simcox.alison@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this Federal Register, EPA is approving the State’s SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules Section of this Federal Register.


H. Curtis Spalding,
Regional Administrator, EPA New England.

[FR Doc. 2016–21011 Filed 8–31–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 013—Autoimmune Disease; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Denial of petition for addition of a health condition.

SUMMARY: On April 4, 2016, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 013) to add “relapsing remitting multiple sclerosis (autoimmune)” to the List of WTC-Related Health Conditions (List). Upon reviewing the information provided by the petitioner, the Administrator determined that Petition 013 is not substantially different from Petitions.
007, 008, 009, and 011, which also requested the addition of autoimmune diseases, including various subtypes. The Administrator recently published responses to the four previous petitions in the Federal Register and has determined that Petition 013 does not provide additional evidence of a causal relationship between 9/11 exposures and autoimmune diseases, including multiple sclerosis. Accordingly, the Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of September 1, 2016.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C–46, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email NIOSHreg@cdc.gov.

SUPPLEMENTARY INFORMATION:

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113), added Title XXXIII to the Public Health Service Act (PHS Act), establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. Within 90 days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) and 42 CFR 88.17: (1) Request a recommendation of the STAC; (2) publish a proposed rule in the Federal Register to add such health condition; (3) publish in the Federal Register the Administrator’s determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the Federal Register a determination that insufficient evidence exists to take action under (1) through (3) above. However, in accordance with 42 CFR 88.17(a)(4), the Administrator is required to consider a new petition for a previously-evaluated health condition determined not to qualify for addition to the List only if the new petition presents a new medical basis—evidence not previously reviewed by the Administrator—for the association between 9/11 exposures and the condition to be added.

B. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or her designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program.

C. Petition 013

On April 4, 2016, the Administrator received a petition from a responder in the WTC Health Program to add “relapsing remitting multiple sclerosis” to the List (Petition 013). Because the petitioner identified the requested health condition as “the autoimmune disease of multiple sclerosis” in the petition narrative and used a study of autoimmune diseases among WTC responders to provide the medical basis for the petition, the Administrator determined that the petitioned health condition is “autoimmune diseases, including multiple sclerosis.”

This is the fifth petition to the Administrator requesting the addition of autoimmune diseases, including various subtypes, to the List; each of the first four autoimmune disease petitions were denied due to insufficient evidence, as described in respective Federal Register notices (FRNs). The medical basis for a potential addition to the List may be demonstrated by reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors.

In accordance with WTC Health Program policy, the Science Team reviews references for relevance, and relevant studies are further reviewed for quality and quantity. The current petition, Petition 013, presented five references to support the request to add “relapsing remitting multiple sclerosis (autoimmune)” to the List.

Petition 013 references 1, 2, and 4 are links to the same newspaper article announcing the online publication of a study published in 2015. Petition 013

2 See Petition 013, WTC Health Program: Petitions Received, http://www.cdc.gov/wtc/received.html.

3 Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111–347 do not pertain to the WTC Health Program and are codified elsewhere.


6 Information is determined to be relevant if it is presented in peer-reviewed, published, epidemiologic studies of the health condition in 9/11-exposed populations.

reference 3 is a different newspaper article announcing the online publication of the same study. These four references identify a 2015 study by Webber et al., a peer-reviewed, published epidemiologic study of autoimmune diseases among 9/11-exposed responders and survivors, titled “Nested Case-Control Study of Selected Systemic Autoimmune Diseases in World Trade Center Rescue/Recovery Workers.” The 2015 Webber et al. study has already been evaluated by the Administrator in consideration of the other four autoimmune disease petitions, and is discussed below. The fifth reference provided in Petition 013 does not specifically identify a peer-reviewed, published epidemiologic study of the health condition among 9/11-exposed populations, nor is it a clinical case report of the health condition in WTC responders or survivors. Petition 013 reference 5 is a link to the proceedings of a research meeting conducted by the WTC Health Program in 2014. Two abstracts found in the proceedings address the topic of autoimmune disease among the 9/11 population—“Autoimmune Disease among WTCHR [World Trade Center Health Registry] Registrants: Survey Design and Preliminary Response Rates,” and “Post-9/11 Incidence of Systemic Autoimmune Diseases in the FDNY Cohort.” The former abstract references an unpublished study; because unpublished studies do not meet the Program’s standard for relevance, it was not further considered. The latter abstract describes a study that resulted full in the April 2016 FRN for Petition 011. As discussed in the April 2016 FRN finding of insufficient evidence for Petition 011, the 2015 Webber et al. study looked at the association between 9/11-related exposures and systemic autoimmune diseases. It was found to be a published, peer-reviewed epidemiologic study of autoimmune diseases in the 9/11 population, and therefore deemed relevant. However, the study was found to exhibit substantial limitations, and it was ultimately concluded not to have the potential to form the basis for a decision on whether to propose adding autoimmune diseases to the List of WTC-Related Health Conditions.

In addition to a review of the studies presented in Petition 013, the WTC Health Program Science Team conducted a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the condition to the List. A previously conducted literature review for autoimmune diseases in response to Petition 007 included all of the autoimmune conditions in the 2015 Webber et al. study. In reviewing Petition 013, the Science Team conducted a search to update the results of the previous literature review for all of the types of autoimmune diseases identified in the 2015 Webber et al. study, and also conducted a separate search for published, peer-reviewed studies of multiple sclerosis in 9/11 populations. The Science Team identified five additional references to review for relevance. Of the five additional references, only one study, published in 2016 by Webber et al., was found to be a relevant, published, peer-reviewed study of autoimmune diseases in 9/11-exposed populations. No published, peer-reviewed epidemiologic studies of multiple sclerosis in 9/11-exposed populations were identified in the literature search.

The 2016 Webber et al. study is a follow-up to the 2015 Webber et al. study discussed above. The 2016 Webber et al. study looked at the same cohort of FDNY rescue/recovery workers included in the 2015 study to estimate the incidence of systemic autoimmune diseases in the cohort of FDNY rescue/recovery workers and to compare the FDNY incidence rates to demographically similar men and other published rates. This additional reference, the 2016 Webber et al. study, was also identified as relevant in the literature search for Petition 011. As a result, it was further reviewed in the April 2016 FRN for Petition 011 and, along with the 2015 Webber et al. study, evaluated for quantity and quality to provide a sufficient basis for deciding whether to propose an addition to the List. Significant limitations, discussed in the April 2016 FRN for Petition 011, led the WTC Health Program to conclude that the 2015 Webber et al., and the 2016 Webber et al. study together do not have the potential to provide a basis for a decision on whether to propose adding autoimmune diseases to the List.

All of the references and potential medical bases presented in Petition 013 were previously identified and assessed in Petition 011; as discussed above, these medical bases had significant limitations that prevented them from having the potential to provide a basis to propose adding autoimmune diseases to the List. The Science Team did not find any information during their review of Petition 013 which would alter the assessment of the previously reviewed studies. Moreover, none of the studies identified, including the 2015 and 2016 Webber et al. studies, include multiple sclerosis. Thus, no evidence was found specific to multiple sclerosis which would have the potential to form the basis for a decision on whether to propose adding multiple sclerosis to the List.

D. Administrator’s Determination on Petition 013

The Administrator has established a policy for evaluating whether to propose the addition of non-cancer health conditions to the List of WTC-Related Health Conditions. Petition 013 requested the addition of “relapsing remitting multiple sclerosis (autoimmune)” to the List. The Administrator previously reviewed the category of “autoimmune diseases,” which includes multiple sclerosis, for Petitions 007, 008, 009, and 011. Neither the references included in Petition 013 nor the studies found in the literature review conducted by the Science Team presented evidence of a causal association between 9/11 exposures and
autoimmune diseases, including multiple sclerosis.

The Administrator initially reviewed the findings presented in the 2015 Webber et al. study in response to Petition 007, which also requested the addition of autoimmune diseases, including rheumatoid arthritis and connective tissue diseases. In that review, due to limitations in the 2015 Webber et al. study, the Administrator determined that insufficient evidence existed to take any of the following actions: Propose the addition of autoimmune diseases to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)); publish a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)); or request a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)). The 2015 Webber et al. study was also presented as evidence to support the Petition 008 request for autoimmune disorders, specifically encephalitis of the brain, the Petition 009 request for autoimmune disorders, including multiple sclerosis, as well as the Petition 011 request for autoimmune disorders, including lupus and rheumatoid arthritis. The 2016 Webber et al. study was also presented as evidence to support Petition 011. As concluded in the April 2016 FRN for Petition 011, the two Webber et al. studies, taken together, while meeting the relevance threshold of being useful if submitted within 30 days of publication.

Finding no additional relevant studies with regard to Petition 013, the Administrator has accordingly determined that insufficient evidence exists to take further action at this time, including either proposing the addition of autoimmune diseases, including multiple sclerosis, to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) is unwarranted.

For the reasons discussed above, the request made in Petition 013 to add “relapsing remitting multiple sclerosis (autoimmune)” to the List of WTC-Related Health Conditions is denied.

The Administrator will continue to monitor the scientific literature for publication of the results of the ongoing WTC Health Registry study discussed above (reference 5 in the petition) and any other studies that address autoimmune diseases among 9/11-exposed populations.

John Howard,
Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.