

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 22, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1320 is added to subpart D to read as follows:

§ 180.1320 Methyl jasmonate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of methyl jasmonate in or on all food commodities when methyl jasmonate is applied pre-harvest.

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BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

World Trade Center Health Program; Certification of Breast Cancer in WTC Responders and Survivors Exposed to PCBs

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Change in certification requirements.

SUMMARY: On September 12, 2012, HHS published a final rule in the **Federal Register** adding certain types of cancer to the List of World Trade Center (WTC)-Related Health Conditions (List) established in the WTC Health Program regulation. Breast cancer was included on the List, although only individuals

experiencing nighttime sleep disruption as a result of response and cleanup activities involving shiftwork are currently considered to have experienced exposure relevant for certification. A recent publication in *The Lancet Oncology* by the International Agency for Research on Cancer (IARC) concludes that there is *limited* evidence that polychlorinated biphenyls (PCBs) cause breast cancer in humans. As described below, the WTC Program Administrator (Administrator) has found that PCBs were present in WTC dust in the New York City disaster area and, accordingly, the Program will now certify breast cancer in eligible WTC responders and survivors who were exposed to either shiftwork/nighttime sleep disruption or PCBs as a result of the 9/11 attacks.

DATES: This change in certification requirements is effective April 17, 2013.

FOR FURTHER INFORMATION CONTACT: Paul Middendorf, Senior Health Scientist, 1600 Clifton Rd. NE., MS: E-20, Atlanta, GA 30329; telephone (404)498-2500 (this is not a toll-free number); email pmiddendorf@cdc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

On September 7, 2011, the Administrator received a written petition to add cancers to the List of WTC-Related Health Conditions in 42 CFR 88.1 (Petition 001). On October 5, 2011, the Administrator formally exercised his option to request a recommendation from the WTC Health Program Scientific/Technical Advisory Committee (STAC) regarding the petition.¹ The Administrator requested that the STAC “review the available information on cancer outcomes associated with the exposures resulting from the September 11, 2001, terrorist attacks, and provide advice on whether to add cancer, or a certain type of cancer, to the List specified in the Zadroga Act.” Following three public meetings where the Committee deliberated on the issues, the STAC submitted its recommendation on Petition 001 to the Administrator on April 2, 2012. After considering the STAC’s recommendation, the Administrator issued a notice of proposed rulemaking on June 13, 2012 [77 FR 35574]. On September 12, 2012, HHS published a final rule in the **Federal Register** adding certain types of cancer to the List of WTC-Related Health Conditions in 42 CFR 88.1 [77 FR 56138]. On October 12, 2012, HHS published a **Federal Register** notice to

correct errors in Table 1 of the final rule (the list of cancers covered by the Program) [77 FR 62167].

B. Administrator’s Determination on the Inclusion of Female Breast Cancer

In the final rule, the Administrator established a four-pronged Methodology for evaluating whether to add certain types of cancer to the List: Epidemiologic Studies of September 11, 2001 Exposed Populations (Method 1); Established Causal Associations (Method 2); Review of Evaluations of Carcinogenicity in Humans, requiring both Published Exposure Assessment Information, and Evaluation of Carcinogenicity in Humans from Scientific Studies (Method 3, including criteria 3A and 3B); and Review of Information Provided by the WTC Health Program Scientific/Technical Advisory Committee (Method 4). A full narrative description and graphic of the Methodology were published in the final rule [77 FR 56138, 56142–56143 (September 12, 2012)].

At the time of the Administrator’s deliberation, breast cancer was determined to meet Method 4 (the STAC had provided a reasonable basis for its inclusion on the List). In its April 2, 2012 recommendation, the STAC had reported that:

There is evidence of PCB [polychlorinated biphenyl] exposures to WTC responders and survivors based on air samples, window film samples and one biomonitoring study. Studies have linked total and congener-specific PCB levels in serum and adipose tissue with breast cancer, although evidence has been conflicting. PCBs and some other substances at the WTC site are endocrine disruptors. Breast cancer risks are highly related to hormonal factors, including endogenous and exogenous estrogens, and could plausibly be affected by endocrine disruptors. A recent study found that PCBs enhanced the metastatic properties of breast cancer cells by activating rho-associated kinase. Shiftwork involving circadian rhythm disruption has been classified by IARC as probably carcinogenic to humans, based in part on epidemiologic studies associating shiftwork with increased risks of breast cancer. Both shiftwork and long shifts were common for workers involved in rescue, recovery, clean up, restoration and other activities at the WTC site.² [references omitted]

Although the STAC specified that PCBs might be causally associated with breast cancer, the Committee provided stronger evidence (IARC classification as a carcinogen) that shiftwork

² STAC [World Trade Center Health Program Scientific/Technical Advisory Committee] [2012]. Letter from Elizabeth Ward, Chair to John Howard, MD, Administrator. This letter is included in NIOSH Docket 257, <http://www.cdc.gov/niosh/docket/archive/docket257.html>.

¹ See 42 CFR 88.17(a)(2)(i).

involving circadian rhythm disruption, as a 9/11 exposure, could be associated with breast cancer.³ For that reason, the Administrator determined that breast cancer would be included on the List, but that the relevant exposures would be limited to nighttime sleep disruption related to response and cleanup activities (including shiftwork). Accordingly, the WTC Health Program has only considered exposure to nighttime sleep disruption related to response and cleanup activities when certifying breast cancers for treatment in WTC responders and survivors.

C. New Information on Breast Cancer and PCBs

On March 15, 2013, the IARC Monograph Working Group announced a change in its classification of polychlorinated biphenyls (PCBs). According to the Working Group's article, published in *The Lancet Oncology*,⁴ a review of more than 70 epidemiological studies led IARC to determine that the studies provided limited evidence of increased risks for breast cancer for individuals with exposures to PCBs.⁵

In reviewing this new information, the Administrator finds that all of the criteria in Method 3 supporting the addition of breast cancer to the List based on PCB exposures are now satisfied: PCBs have been reported in several exposure assessment studies of

responders or survivors of the September 11, 2001, terrorist attacks in New York City (Method 3A);⁶ NTP identified PCBs as reasonably anticipated to be a human carcinogen⁷ and IARC has recently found limited evidence that PCBs cause breast cancer (Method 3B).

Consequently, the Administrator finds that PCB exposures associated with the 9/11 attacks (including response and remediation activities) qualify as another exposure basis—in addition to nighttime sleep disruption related to response and cleanup activities (including shiftwork)—for certifying a member's breast cancer for treatment.

D. Effect on Breast Cancer Coverage

As a result of this finding by the Administrator, eligible responders and survivors who experienced the requisite exposure to either nighttime sleep disruption related to response and cleanup activities (including shiftwork) or PCBs (in dust and smoke) resulting from the 9/11 attacks may be certified for treatment of breast cancer.

Dated: April 11, 2013.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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ENVIRONMENTAL PROTECTION AGENCY

48 CFR Part 1552

[EPA-HQ-OARM-2012-0196; FRL-9800-6]

EPAAR Clause for Printing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

⁶ Butt CM, Diamond ML, Truong J, Ikonomou MG, Helm PA, Stern GA [2004]. Semivolatile organic compounds in window films from lower Manhattan after the September 11th World Trade Center attacks. *Environmental Science & Technology*. 38(13):3514-3524.

Lorber M, Gibb H, Grant L, Pinto J, Pleil J, Cleverly D [2007]. Assessment of inhalation exposures and potential health risks to the general population that resulted from the collapse of the World Trade Center towers. *Risk Anal* 27(5):1203-21.

Lioy PJ, Gochfeld M [2002]. Lessons learned on environmental, occupational, and residential exposures from the attack on the World Trade Center. *Am J Ind Med* 42(6):560-565.

⁷ NTP (National Toxicology Program) [2011]. 12th Report on Carcinogens. National Toxicology Program, Public Health Service, U.S. Department of Health and Human Services, Research Triangle Park, NC. <http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/PolychlorinatedBiphenyls.pdf>. Accessed March 28, 2013.

³ Shiftwork involving circadian rhythm disruption has been classified by IARC as *probably* carcinogenic based in part on limited evidence in humans demonstrating an increased risk of breast cancer among shiftworkers who work at night. IARC notes that mechanistic studies suggest that exposure to light at night may increase the risk of breast cancer by suppressing the normal nocturnal production of melatonin, which in turn, may alter gene expression in cancer-related pathways [Straif, et al. 2007]. NTP has not yet examined the evidence for an association of shiftwork and breast cancer, however, NTP recently requested comment from the public on whether shiftwork involving light at night should be nominated for possible review for future editions of the RoC. [NTP 2012] The Administrator was not aware of any published exposure assessment study of shiftwork and 9/11, although the Administrator was aware that extended work hours for many responders occurred at all three 9/11 sites over several months. Thus the evidence supporting an association between shiftwork and breast cancer did not meet all of the requirements of Method 3; however, the Administrator felt the STAC's recommendation and support for an association between shiftwork and female breast cancer was sufficient to add breast cancer to the List of WTC-Related Health Conditions based on Method 4.

⁴ Lauby-Secretan B, Loomis D, Grosse Y, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L, Guha N, Baan R, Mattock H, Straif K (on behalf of IARC Monograph Working Group) [2013]. Carcinogenicity of Polychlorinated Biphenyls and Polybrominated Biphenyls. *The Lancet Oncology* 14(4):287-288.

⁵ According to the Lancet article, the Working Group's assessments will be published as volume 107 of the IARC Monographs.

SUMMARY: The Environmental Protection Agency (EPA) amends the EPA Acquisition Regulation (EPAAR) to update policy, procedures, and contract clauses. The final rule provides updates to outdated information previously in the EPAAR *Printing* clause.

DATES: This final rule is effective on April 17, 2013.

ADDRESSES: *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 Office of Environmental Information (OEI) Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The 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 EPA Docket Center is (202) 566-1752. This Docket Facility is open from 8:30 a.m. to 4:30 p.m. Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Thomas Valentino, Policy, Training, and Oversight Division, Office of Acquisition Management (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202-564-4522; email address: valentino.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 2011 the EPA reviewed EPAAR clause 1552.208-70, *Printing*. Review was performed to reconsider the electronic reproduction threshold under which vendors may provide contract deliverables without violating mandatory printing source requirements. Reconsideration of the reproduction threshold was warranted given the ease with which electronic media may be reproduced. The clause is also being updated to clarify that EPA's Print Management Team is the processing office responsible for clause printing requirement waivers provided by the Joint Committee on Printing. Finally, the definition of non-paper copies that the contractor may provide has been expanded to include other types of portable electronic media in addition to compact discs. As such, the