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:


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.

[FR Doc. 2013–08829 Filed 4–16–13; 8:45 am]

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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 exposure to PCBs 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.

SUPPLEMENTAL 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. 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, the Administrator formally 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.

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...
involving circadian rhythm disruption, as a 9/11 exposure, could be associated with breast cancer. 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, 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.

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); NTP identified PCBs as reasonably anticipated to be a human carcinogen 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.