

ILLINOIS POLLUTION CONTROL BOARD
December 20, 2007

IN THE MATTER OF:)
)
PETITION OF BIOMEDICAL) AS 08-6
TECHNOLOGY SOLUTIONS INC. FOR AN) (Adjusted Standard – PIMW)
ADJUSTED STANDARD FROM 35 ILL.)
ADM. CODE 1422)

ORDER OF THE BOARD (by N.J. Melas):

On November 28, 2007, Biomedical Technology Solutions, Inc. (BMTS) filed a petition for a statewide adjusted standard from the testing requirements for units treating potentially infectious medical waste (PIMW) at 35 Ill. Adm. Code 1422.Appendix A, Table B. On December 12, 2007, BMTS filed the proof of timely publication of notice of the petition's filing by advertisement in a newspaper of general circulation in the area likely to be affected by the proposed adjusted standard. See Section 28.1(d)(1) of the Environmental Protection Act (Act)(415 ILCS 5/28.1(d)(1) (2006)) and Sections 104.408 and 104.410 of the Board's procedural rules (35 Ill. Adm. Code 104.408, 104.410). BMTS filed certificates of publication with the Board stating that notice was published in both the *Chicago Tribune* and the *State Journal Register* on December 6, 2007. See 35 Ill. Adm. Code 104.410.

BMTS has waived hearing on the petition, although any person may request a public hearing on the petition on or before December 27, 2007. See 35 Ill. Adm. Code 104.420. The Recommendation of the Illinois Environmental Protection Agency (Agency) is currently due to be filed on January 7, 2008 (*i.e.* the first business day following the 45th day after the petition's filing). See 35 Ill. Adm. Code 101.300(a), 104.416(a)).

As explained in more detail below, the Board today accepts the petition, finding that it meets the content requirements of Section 104.406 of the Act. But since hearing is waived, the Board directs BMTS to file an amended petition clarifying whether the language of the adjusted standard best references the requested indicator organism as *Bacillus atrophaeus* (ATCC 9372) or *Bacillus subtilis* var. *niger* (ATCC 9372). Given the smallness of the requested technical clarification, the Board requests BMTS to file its amended petition on or before January 7, 2008. The Agency is accordingly given additional time to file its Recommendation, which is now due January 22, 2008. The parties are directed to seek any extension of these dates from the hearing officer assigned by the Board to manage this case (as well as to hold any hearing that may be timely requested).

THE PETITION

BMTS, based in Colorado, is pursuing the Illinois market to sell its Demolizer® unit for treating PIMW. The Demolizer® unit is about the size of a microwave and is intended for onsite use by businesses that produce low volumes of medical wastes, such as nursing homes and dental

offices. Dry heat is used to sterilize PIMW, including needles, and render it into a nonrecognizable solid waste that can then be disposed of as any other refuse.

The Illinois PIMW regulations at 35 Ill. Adm. Code 1422. Appendix A include test procedures for verifying effective sterilization using an Initial Efficacy Test (IET). Section 1422. Table B lists three indicator microorganisms to be used in the IET, two of which are not appropriate for validating dry heat systems like the Demolizer®, and one (*Bacillus subtilis*, ATCC 19659) of which, according to BMTS, is no longer commercially available in a certified form. Moreover, according to BMTS, *Bacillus subtilis*, ATCC 19659 is not the biological indicator prescribed for dry-heat sterilization among domestic or international standards organizations.

BMTS requests an adjusted standard to use a different indicator (*Bacillus subtilis* var. *niger* ATCC 9372) that is commercially available. Without some form of regulatory relief from the efficacy testing requirement to sell the Demolizer® unit in Illinois, BMTS states it would need to spend \$130,000 to \$320,000 to grow and certify a custom batch of the ATCC 19659 indicator.

CLARIFICATION REQUEST

The Board notes that BMTS had previously filed a petition for variance seeking a change in the regulations. When BMTS did not file an amended petition specifying a compliance plan as requested in the Board's order of July 20, 2007, the Board dismissed the petition. Biomedical Technology Solutions, Inc. v. IEPA, PCB 07-149 (orders of July 20, 2007 and September 20, 2007). Although BMTS could have filed a petition for rulemaking under Section 27 of the Act (415 ILCS 5/27 (2006)), the Board finds that the relief requested here is available to BMTS by way of this adjusted standard petition under Section 28.1 of the Act (415 ILCS 5/28.1 (2006)).

For the indicator organisms currently listed in Part 1422, BTMS' variance petition in PCB 07-149 requested substitution of *Bacillus atrophaeus* (ATCC 9372), whereas the instant adjusted standard petition requests substitution of *Bacillus subtilis* var. *niger* (ATCC 9372). But, BTMS also states that *Bacillus subtilis* var. *niger* was formally reclassified as *Bacillus atrophaeus* in the International Journal of Systematic and Evolutionary Microbiology (2001), 51, 35-37 (Petition at 11.) This would seem to make the use of the language requested in the PCB 07-147 variance petition (*Bacillus atrophaeus*) preferable to that requested in the adjusted standard petition (*Bacillus subtilis* var. *niger*).

The Board directs BTMS to address the issue of the preferred nomenclature in an amended petition to be filed on or before January 7, 2008. The amended petition need not contain any of the other information, attachments, or exhibits contained in the November 28, 2007 petition. The amended petition should confine itself solely to the issue of the proper naming of the substitute indicator organism.

Under these circumstances, given the limited nature of the clarification requested, the Board on its own motion grants the Agency additional time for the filing of its Recommendation, now due January 22, 2008. In its Recommendation, the Agency too is requested to address the

specific language to be used in any adjusted standard granted in this proceeding.

Unless a timely request for hearing on BTMS' petition is filed with the Board on or before December 27, 2007, the Board does not presently plan to order a hearing in this matter. The Board presently intends to issue its final opinion and order based on the timely filed pleadings of BTMS and the Agency. The parties may seek extensions of the filing dates contained in this order from the hearing officer, who is authorized to grant appropriate requests without further action of the Board.

IT IS SO ORDERED.

I, John Therriault, Assistant Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above order on December 20, 2007, by a vote of 4-0.



John Therriault, Assistant Clerk
Illinois Pollution Control Board