

ILLINOIS POLLUTION CONTROL BOARD
March 5, 2019

IN THE MATTER OF)
)
AMENDMENTS TO DEFINITION OF) R18-29 (Subdocket B)
"CLASS 4 ETIOLOGICAL AGENT,) (Rulemaking – Biological Materials)
35 ILL. ADM. CODE 1420.102)

HEARING OFFICER ORDER

The Board, on May 10, 2018, proposed amendments to its potentially infectious medical wastes (PIMW) rules for hearing and public comment. On February 14, 2018, the Board adopted amendments for first notice publication to Parts 1420, 1421, and 1422 (35 Ill. Adm. Code 1420, 1421, and 1422) of its PIMW regulations. In the first notice order, the Board opened this subdocket to consider substantive amendments to the definition of "Class 4 etiological agent." Amendments to 35 Ill. Adm. Code Subtitle M, R18-29, slip op. at 3 (Feb. 14, 2019).

The Board found that the definition of "Class 4 etiological agent" under 35 Ill. Adm. Code 1420.102 is outdated. *Id.* After considering public comments from the Illinois Environmental Protection Agency (Agency) and Illinois Health and Hospital Association (IHA), the Board concluded non-substantive amendments would not adequately update the definition, substantive revisions would fall outside the scope of R18-29, and there was not enough information in the record to determine an adequate substantive revision. *Id.* The Board explained,

[t]he Board is concerned that deleting the list following the preamble definition of "Class 4 etiological agent" as suggested by IEPA, while relying on the Board note to provide context for the definition would require the Board to incorporate both documents currently in the Board note. Similarly, it is not clear whether IHA's suggestion to reference the Federal Select Agents and Toxins List means incorporating 7 CFR 331, 9 CFR 121, and 42 CFR 73, which are the U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) regulations. Further, a cursory review of the Federal Select Agent Program's website hosted by HHS, [Center for Disease Control (CDC)], and USDA suggests "Tier 1 Agents" within the select agents listing. *See* <https://www.selectagents.gov/SelectAgentsandToxinsList.html> (last visited Feb. 13, 2019). If the definition of "Class 4 etiological agent" does not provide a list, as the Agency suggests, then the addition of the Federal Select Agents and Toxins List will also require incorporation by reference. *Id.*

Any interested person is invited to provide comments on updating the definition of "Class 4 etiological agent." Based on the Board's discussion above, comments should address whether the Board should incorporate by reference the two documents in the Board Note to the definition of "Class 4 etiological agent": the CDC's "Classification of Human Etiologic Agents on the Basis of Hazard" and the CDC/NIH document "Biosafety in Microbiological and Biomedical

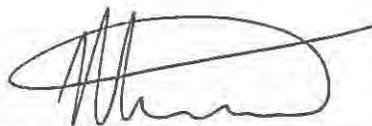
Laboratories.” If so, comments should include proposed language to amend the definition of “Class 4 etiological agent” to refer to the specific documents incorporated by reference.

Public comments should also address whether the Board should include the Federal Select Agents and Toxins List in the definition and in what form. Specifically, should the Board identify some or all the agents and toxins from the list and include them in the definition; or should the Board incorporate some or all the federal regulations of the Federal Select Agent Program by reference and amend the definition to refer to the regulations. Again, the comments should include proposed language to amend the definition of “Class 4 etiological agent.”

When the Board opened this subdocket all the comments, testimony, and filings in R18-29 were incorporated into this docket. Amendments to 35 Ill. Adm. Code Subtitle M, R18-29, slip op. at 3. Because the Board already held two hearings in R18-29, no additional hearings will be scheduled for this subdocket unless the Board finds that hearings would facilitate the submission of views and comments, or unless requested by any interested person in compliance with the IAPA or the Board’s procedural rules. *See* 5 ILCS 100/5-40(b) (2016); 35 Ill. Adm. Code 102.412(b).

Comments and any related exhibits will be accepted until close of business Monday, May 6, 2019.

IT IS SO ORDERED.



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