

ILLINOIS POLLUTION CONTROL BOARD  
February 14, 2019

IN THE MATTER OF )  
 )  
AMENDMENTS TO 35 ILL. ADM. CODE ) R18-29  
SUBTITLE M: BIOLOGICAL MATERIALS ) (Rulemaking – Biological Materials)

Proposed Rule. First Notice.

OPINION AND ORDER OF THE BOARD (by C.K. Zalewski):

The Board opened this docket under Part 102 of its procedural rules (35 Ill. Adm. Code 102, Subpart B) and Sections 27 and 28 of the Illinois Environmental Protection Act (Act) (415 ILCS 5/27, 28 (2016)) to amend the Board’s potentially infectious medical waste (PIMW) rules (35 Ill. Adm. Code: Subtitle M). The Board’s PIMW rules have not been amended since their adoption in 1993 (Potentially Infectious Medical Waste; Treatment, Storage, and Transfer Facilities and Transportation, Packaging, and Labeling: 35 Ill. Adm. Code 1420, 1421, & 1422, R91-20 (Jun. 17, 1993)), despite the enabling statute (415 ILCS 5/56 – 56.7 (2016)) having been substantively amended three times during the ensuing 25 years (P.A. 92-574 (eff. June 26, 2002); P.A. 94-641 (eff. Aug. 22, 2005); and P.A. 99-82 (eff. July 20, 2015)). Recognizing that some of its rules were no longer current due to changing technology and the passage of time, the Board began reviewing its rules in the summer of 2016, to streamline, update, and overhaul them.

Today, the Board proposes amendments for first notice publication. In this order, the Board provides the procedural history of the hearings and public comments, and then discusses the substance of the public comments and the first notice amendments to the PIMW rules. The proposed amendments appear as an addendum to this order.

**HEARINGS AND PUBLIC COMMENT**

The Board proposed amendments to its PIMW rules for hearing and public comment on May 10, 2018. The first hearing took place on September 11, 2018, and the Board received the transcript (Tr.1) on September 13, 2018. Al Burson, corporate director of incinerator compliance for Stericycle, Inc. gave testimony. Tr.1 at 6-14. The second hearing took place on October 17, 2018. The Board received the transcript (Tr.2) on October 18, 2018. No testimony was offered, but the Board did receive spoken public comment on behalf of Stericycle. The hearing officer set November 8, 2018 as the deadline for post-hearing comments.

Section 27(b) of the Act requires that the Board request the Department of Commerce and Economic Opportunity (DCEO) to conduct a study of the economic impact of certain proposed rules prior to their adoption. The Board sent the request to DCEO on May 10, 2018. The hearing officer noted the Board received no reply from DCEO at both hearings. Tr.1 at 5; Tr.2 at 5. No comments were offered on the Board’s request to the DCEO.

The Board received four written comments. On September 13, 2018, the Board docketed an email exchange between the court reporter and the Board (PC 3). The Board received written comments on the amendments from Stericycle, Inc. (Stericycle) (PC 1) and the Illinois Environmental Protection Agency (IEPA or Agency) (PC 2) prior to the first hearing. The Board also received written comments from the Illinois Health and Hospital Association (IHA) (PC 4) after the second hearing.

### **PROPOSED AMENDMENTS**

The PIMW rules are in Parts 1420, 1421, and 1422, within Subtitle M of the Illinois Administrative Code's Title 35. These provisions address definitions, prohibitions, permitting, and minimum standards for treatment, packaging, storage, transportation, and disposal.

The Board limited the scope of this proceeding to non-substantive revisions to the PIMW rules. Thus, the Board's proposed amendments remove legalese, redundant and superfluous language, as well as reorganize some provisions for clarity. The amendments also change citations and regulatory language to comply with the style requirements of the Illinois Administrative Code.

The proposed rulemaking included the entire Subtitle M, to permit the public to address those Sections where the Board did not propose amendments. No public comments were received on these amendments, therefore Sections 1421.110, 1421.120, 1421.130, 1421.Illustration A, 1422.110, 1422.120, and 1422.Table A and Table B are not included in this first notice proposal. 35 Ill. Adm. Code 1421.110, 1421.120, 1421.130, 1421.Illustration A 1422.110, 1422.120, 1422.Table A, and 1422.Table B.

The Board also proposed making three deletions. In Section 1420.102, the Board proposed removing the last sentence in the definition of "reusable container" because it provides no additional clarity. In addition, the Board proposed repealing Section 1421.101 (Compliance Date) and Section 1422.101 (Compliance Date) because they establish compliance dates that passed in 1993. And the Board deleted subsection (c) of Section 1422.123—subsection (c) exempts from subsection (b)'s Initial Efficacy Test requirements those treatment units operating before the PIMW rules took effect 25 years ago. No public comments were received on these specific deletions; therefore, the first notice amendments reflect the deletions.

In addition to seeking public comment on the proposal generally, the Board asked five specific questions. The written public comment received by the Board addressed some or all the questions, as well as additional issues. The Board will first address the comments on each question. Then the Board will address all additional matters raised in the public comments.

#### **Section 1420.102's Definition of "Class 4 etiological agent"**

1. *Is the list of viral agents complete and consistent with current Center for Disease Control and National Institute of Health listings?*

The Board received comments from the Agency and IHA addressing the first question. The Agency states that the list of viral agents in the definition of “Class 4 etiological agent” is no longer consistent with the Center for Disease Control (CDC) and National Institute of Health (NIH) practice. PC 2, at 1. The Agency explains that the CDC and NIH now rely on four “risk groups” to classify diseases and removed listings of diseases. *Id.* The Agency suggests deleting the listing of diseases and define “Class 4 etiological agent” as “a pathogenic agent that is extremely hazardous to laboratory personnel or that may cause serious epidemic disease.” *Id.*

The IHA suggests that, in addition to referencing the CDC and NIH listings for viral agents, the Board should include the Federal Select Agents and Toxins List, which the IHA states is a broader list of viral agents. PC 4 at 1. Other than providing the name of the list, IHA did not cite to a regulation, publication, or website. Though the Board may incorporate by reference standards, regulations, or rules of an agency of the United States, the Board must identify the location of the incorporated matter and have a full copy available at the Board’s office.

The Board declines to accept either the Agency’s or IHA’s suggestion. The 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, 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. Incorporation of the publications already in the Board Note or the Federal Select Agents and Toxins List is a substantive change to the rules beyond the scope of this rulemaking.

It is clear to the Board, however, that a substantive consideration of the definition of “Class 4 etiological agent” is necessary, as both the Agency and IHA have identified the existing definition as outdated. The Board directs the Clerk to open a Subdocket B in this proceeding, which will include all the comments, testimony, and filings in this docket. The subdocket will be limited to the substantive review of the definition of “Class 4 etiological agent.” If the Board decides to substantively amend the definition, then the Board will proceed with first notice publication in the *Illinois Register*. The Board directs the hearing officer to set procedures for comment in this subdocket.

2. *Do the sources relied on in the Board’s Note need to be updated or supplemented?*

The Board received comments from IEPA and Stericycle addressing the second question. The Agency explains that one of the incorporated documents has been renamed since the PIMW rules were adopted and should be amended. Specifically, the document “Classification of

Etiologic Agents on the Basis of Hazard” is now titled “Classification of Human Etiologic Agents on the Basis of Hazard.” The first notice proposal reflects this change.

### **Section 1420.103’s Incorporation by Reference**

3. *Does the list of publications need to be updated by adding a publication, removing a publication, or replacing a listed publication with a more current version?*

The Board received two comments responding to the third question. The Agency states that the Board’s proposed amendments properly update the publications incorporated by reference, and no other publications need to be added. PC 2 at 1-2. Stericycle commented that the Board should update its regulations for references to the current federal regulations that are applicable, duplicative and in some cases pre-emptive. PC 1 at 1. Stericycle recommended that the Board consider updating its sources and publications referenced in the rules. *Id.* But Stericycle did not identify which sources need to be updated or added.

Without a specific proposal to update the current section, the Board’s first notice proposal makes no additional changes to its proposal for public comment on first notice. As noted above, adding new publications to be incorporated by reference would be a substantive change beyond the scope of this rulemaking. The Board is prepared to review its PIMW rules if it can be demonstrated that they are outdated and a proposal for amendment is presented. The Board encourages public comments that provide updated, alternative, or additional publications to be cited if the Board’s PIMW rules need to be updated.

### **Section 1420.104 and “Household Sharps”**

4. *Are “household sharps”—as the term is utilized in Sections 56.1(k) and (l)—“general household waste” and not subject to either 35 Ill. Adm. Code 1422.126 or any other PIMW rules?*
5. *If “household sharps” are not general household waste, are additional amendments to any of the PIMW rules necessary?*

The Board received comments from Stericycle, the Agency, and IHA addressing questions 4 and 5. Both the Agency and IHA commented that household sharps fall under the general household waste exemption in the definition of PIMW in 415 ILCS 5/3.360(b)(1) (2016). IHA argues that because Section 56.1(k) and (l) of the Act (415 ILCS 5/56.1(k) and (l)) concern residents intermingling medical sharps with their recycling, the subject matter of subsections (k) and (l) concern household waste and should therefore be treated under the household waste exemption.

Stericycle’s comments suggest that the Board should consider adopting a new section of rules specific to home-generated sharps. Stericycle notes that opioid and prescription drug abuse continue to be a challenge in the state. Stericycle comments that with new legislation passed, the regulations need to be updated to reflect the legislative changes. PC 1 at 2. Stericycle did not present a specific proposal for consideration.

The Board's proposal for public comment added new subsections (k) and (l) to the proposed amendments to Section 1420.104 (35 Ill. Adm. Code 1420.104(k) and (l)) to reflect the amendments to Section 56.1 of the Act (415 ILCS 5/56.1 (2016)). For first notice, the Board will not include these subsections to the proposed Section 1420.104. If household sharps are general household waste, then they are not subject to these rules. If household sharps are not household waste, then any additional amendments would be substantive and beyond the scope of this rulemaking. Without a proposal to consider, the Board declines to address whether household sharps are PIMW. Of course, the Board's decision not to address this question does not affect Section 56.1(k) and (l)'s prohibitions. 415 ILCS 5/56.1(k) and (l).

### **Additional Issues Raised in Public Comments**

#### **IEPA Revisions to Sections 1420.102, 1422.125(a)(1), and 1422.125(b)(1)**

The Agency identifies three instances where the Board proposes deleting the phrase "at a minimum." PC 2. The Agency recommends retaining the phrase in the definition of "equivalent log kill" (Proposed 35 Ill. Adm. Code 1420.102), Section 1422.125(a)(1), and Section 1422.125(b)(1). The Agency argues that retaining the phrase "at a minimum" "acknowledges that there will be times when the starting value is higher than  $10^6$ ." PC 2.

The use of the phrase "at a minimum" is redundant or superfluous in all three instances. In Sections 1422.125(a)(1) and (b)(1), the phrase "at a minimum" precedes a figure that is the minimum threshold; any number below would be non-compliant. Use of the phrase "at a minimum" is redundant and unnecessary. And striking the phrase "at a minimum" from the definition of "equivalent log kill" does not change the meaning of the sentence, as the Agency suggests. The sentence "the logarithm of the indicator microorganisms that must be killed and correlates to a 6-log reduction of viable test microorganisms" does not set the starting value of the microorganisms. It merely sets the minimum reduction that must be demonstrated. Again, use of the phrase "at a minimum" is redundant and unnecessary. The Board declines to retain the phrase in all three instances.

#### **Stericycle Proposal for Comprehensive Review of PIMW Rules**

Stericycle offered written and spoken public comments, and testimony suggesting that the Board and other relevant agencies consider a comprehensive review of the PIMW rules through a stakeholder process. PC 1; Tr.2; Tr.1. Stericycle explained that there have been several changes in streams of PIMW, changes in healthcare practices, and changes in best management practices for handling and disposing the PIMW. In written and spoken public comment, Stericycle noted the example of Ebola patient waste in 2014, and that the Board's rules are not adequate for these examples. PC 1 at 1; Tr.2 at 8-9. Stericycle suggests that the Board "in the future . . . [consider] maybe a reorganization and [ ] some updates" to the Board's rules. Tr.2 at 7. Mr. Burson explained, "Stericycle believes that a stakeholder process should be implemented between other members of the industry and the Board itself or the agencies involved with it . . . we would like a stakeholder committee or stakeholders to be involved in the process as the change comes about."

Tr.1 at 8.

As noted above, the Board recognizes that the PIMW rules have not been amended since their adoption over 25 years ago and a substantive review may be appropriate. The Board appreciates Stericycle's involvement in this rulemaking and apparent willingness to review the Board's PIMW rules. But this rulemaking is meant to improve accessibility of the rules by simplifying and clarifying language and removing obsolete and redundant language. A comprehensive review of the PIMW rules would exceed the intended scope of this rulemaking. The Board, however, strongly encourages Stericycle, other stakeholders, and the Agency to review the Board's PIMW rules for a comprehensive update that considers the new challenges faced in the industry and best management practices.

### **ORDER**

The Board directs the Clerk to cause first-notice publication in the *Illinois Register* of the proposed rule amendments in the addendum to this order.

For first notice under the Illinois Administrative Procedure Act (IAPA) (5 ILCS 100/5-40(b) (2016)), the Board proposes the rule amendments in the addendum to this order. First notice publication of the proposed amendments in the *Illinois Register* will start the first-notice public comment period of at least 45 days. *See* 35 Ill. Adm. Code 102.604. During that period, anyone may file a public comment on the proposal with the Clerk's Office. Public comments must be filed with the Clerk's Office electronically through the "Clerk's Office On-Line" or "COOL" ([pcb.illinois.gov](http://pcb.illinois.gov)). *See* 35 Ill. Adm. Code 101.302(h), 101.1000, and 102.108(c). Any person unable to file comments through COOL, can contact the Clerk's Office at (312) 814-3461 for assistance or permission to file on paper. *See* 35 Ill. Adm. Code 101.302(h) and 101.1000(c).

Because the Board already held two hearings on this proposal, no additional hearings will be scheduled 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).

IT IS SO ORDERED.

I, Don A. Brown, Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above order on February 14, 2019, by a vote of 5-0.



Don A. Brown, Clerk  
Illinois Pollution Control Board