

ILLINOIS POLLUTION CONTROL BOARD

December 19, 2019

IN THE MATTER OF:)
)
AMENDMENTS TO DEFINITION OF) R20-17
“CLASS 4 ETIOLOGIC AGENT”, 35 ILL.) (Identical-in-Substance
ADM. CODE 1420.102) Rulemaking – Biological Materials)

Proposed Rule. Proposal for Public Comment.

OPINION AND ORDER OF THE BOARD (by A. Palivos):

The General Assembly found in the early 1990s that potentially infectious medical waste (PIMW), if not handled properly, may constitute an environmental or public health problem. 415 ILCS 5/56(a) (2018). To reduce these potential risks, the General Assembly enacted Title XV of the Environmental Protection Act (Act), establishing requirements for handling PIMW responsibly. 415 ILCS 5/56(b) (2018). Title XV mandated that the Board adopt regulations prescribing design and operating standards for all PIMW treatment, storage, and transfer facilities. 415 ILCS 5/56.2(a) (2018). Following this mandate, the Board in 1992 and 1993 adopted regulations applicable to all persons who generate, transport, treat, store, or dispose of PIMW. *See* 35 Ill. Adm. Code 1420, 1421, 1422.

In today’s opinion and order, the Board proposes amendments to update its definition of “Class 4 etiologic agent,” which bears on the definition of PIMW. The Act requires these amendments to reflect the addition of four viral agents, as discussed below.

PIMW is statutorily defined as any one of seven categories of waste generated in connection with medical services, immunization, research, or the production or testing of biologicals. 415 ILCS 5/3.360(a) (2018); *see also* 415 ILCS 5/3.360(b) (2018) (exclusions). This rulemaking concerns one of those seven categories: “isolation waste.” 415 ILCS 5/3.360(a)(6) (2018). Isolation waste includes waste that must be isolated to protect persons from “highly communicable diseases” as identified by the Board in rules adopted under Section 56.2(e) of the Act. *Id.*

In turn, Section 56.2(e) of the Act requires that the Board adopt rules that are “identical in substance” to the list of “etiologic agents identified as Class 4 agents” in the “Classification of Etiological Agents on the Basis of Hazard, 1974,” published by the Centers for Disease Control (CDC). 415 ILCS 5/56.2(e) (2018). The National Institutes of Health (NIH) recently updated that 1974 CDC document by adding four Class 4 etiologic agents. Accordingly, under Section 56.2(e), the Board proposes adding those four agents to the viral agent list within the “Class 4 etiologic agent” definition at 35 Ill. Adm. Code 1420.102: Guanarito virus; Sabia; Ebola Virus; and Equine Morbillivirus.

In this opinion and order, the Board first elaborates on the relevant statutory and regulatory framework, followed by further background on this rulemaking’s objectives. The

Board then discusses the proposed amendments, requests public comment, and concludes with information on how the rulemaking will proceed. The proposed amendments themselves appear in the addendum to this opinion and order.

STATUTORY AND REGULATORY FRAMEWORK

The Board adopted the definition of “Class 4 etiologic agent” in January 1992 in response to Public Act 87-752, which added, among other provisions, Section 56.2(e) to the Act. That legislation mandated that the Board adopt “rules identical in substance to the etiologic agents in Class 4 in a 1974 Centers for Disease Control, Office of Biosafety listing: Classification of Etiologic Agents on the Basis of Hazard.” Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, slip op. at 1 (Jan. 23, 1992). The Board observed that the 1974 CDC document established five classes of etiologic agents, defining “Class 4” etiologic agents as follows:

Class 4: Pathogenic agents that are extremely hazardous to laboratory personnel or that may cause serious epidemic disease. Class 4 Agents include Class 3 Agents derived from outside the U.S. when they are employed in entomological experiments or when other entomological experiments are conducted in the same laboratory area. Class 3 Agents include those that require the most stringent conditions for their containment.¹ *Id.* at 4.

Along with this narrative description, the 1974 CDC document included listings of agents within classes. *Id.*

The Board defined “Class 4 etiologic agent” as “a pathogenic agent that is extremely hazardous to laboratory personnel or that may cause serious epidemic disease.” 35 Ill. Adm. Code 1420.102. The Board’s definition also contains a list of viral agents and a “Board Note.” *Id.* The Board Note clarifies that a “Class 4 agent helps define an ‘isolation waste’ for Section 3.360(a)(6) of the Act.” *Id.* Further, the Board Note explains that the viral agent list contained in the definition of “Class 4 etiologic agent” is derived from the CDC document “Classification of Human Etiologic Agents on the Basis of Hazard” and is supplemented from the CDC/NIH document “Biosafety in Microbiological and Biomedical Laboratories.” *Id.* This definition has not been amended since 1992, except for minor non-substantive changes to its Board Note in Amendments to 35 Ill. Adm. Code Subtitle M: Biological Materials, R18-29 (Aug. 22, 2019).

Generally, Class 4 etiologic agent listings are revised either by the NIH in “NIH guidelines” or jointly by the NIH and CDC in “Biosafety in Microbiological and Biomedical Laboratories” (BMBL) listings. Potentially Infectious Medical Wastes: Etiologic Agents, R91-

¹ “Class 3: Pathogenic agents involving special hazard, or pathogenic agents derived outside the U.S. which require a federal permit for importation, unless the pathogenic agent is specified for higher classification. Class 3 Agents include those for which special conditions for their containment are required.” Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, slip op. at 3-4.

19, slip op. at 5-6. The Board noted in R91-19 that the NIH revised the 1974 CDC list in 1986 in the Department of Health and Human Services' publication entitled "Guidelines for Research Involving Recombinant DNA Molecules." *Id.* at 5. Though this revised listing contained the classification from the 1974 CDC document, Class 4 no longer included Alastrim, smallpox, and whitepox because they were prohibited from study in the United States except at specified facilities. *Id.*

Further, the Board noted that in 1988, the CDC and NIH jointly published the BMBL listing which included a revised version of the 1974 CDC document. Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, slip op. at 5-6. The Board observed that the classification system under the 1988 CDC/NIH BMBL is "more elastic than the 1974 [CDC] Classification." *Id.* at 6. Specifically, the 1988 publication assigned etiologic agents to "biosafety levels" rather than classes. *Id.* Biosafety levels can "change for any specific agent, depending on the laboratory setting and nature of experimentation." *Id.* Accordingly, many Class 4 agents in the 1974 CDC document were placed in different levels in the 1988 BMBL listing. *Id.* Additionally, the 1988 BMBL listing added four new tick-borne viruses that were not part of the CDC's 1974 list. *Id.*

Based on Section 56.2(e) of the Act and the testimony and comments in R91-19, the Board adopted a definition of "Class 4 etiologic agent" using the 1974 CDC document's Class 4 description and agent listing, and including the four additional tick-borne encephalitis viruses from the 1988 CDC/NIH BMBL listing. Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, slip op. at 6-7.

BACKGROUND

The Board recently adopted non-substantive amendments to clarify and streamline its PIMW rules. Amendments to 35 Ill. Adm. Code Subtitle M: Biological Materials, R18-29 (Aug. 22, 2019). In that rulemaking, the Board asked participants to address whether the viral agents listed in the definition of "Class 4 etiologic agent" (35 Ill. Adm. Code 1420.102) are complete and consistent with the current CDC and NIH listings. Amendments to 35 Ill. Adm. Code Subtitle M: Biological Materials, R18-29, slip op. at 3-4 (Feb. 14, 2019). If the Board's definition is not complete and consistent with current CDC and NIH listings, the Board must conduct identical-in-substance rulemaking under Section 56.2(e) of the Act to update the definition. The Board also asked whether the sources relied on in the definition's Board Note should be updated or supplemented. *Id.* at 3.

The Illinois Environmental Protection Agency (IEPA) responded that the list of viral agents contained in the definition of "Class 4 etiologic agent" is neither current nor complete. R18-29 PC 2 at 1.² IEPA stated that the list has been "virtually eliminated" over the past 25

² The citation refers to PC 2 from docket R18-29. The Board directs the Clerk to enter a copy of that public comment into this R20-17 docket as PC 1.

years. *Id.* Instead, the CDC and NIH now rely on four “risk groups” to classify agents and diseases. *Id.* IEPA recommended that the Board retain the existing definition but delete the list of viral agents:

“Class 4 etiologic agent” means a pathogenic agent that is extremely hazardous to laboratory personnel or that may cause serious epidemic disease. *Id.*

However, the Illinois Health and Hospital Association (IHA) stated that using CDC and NIH documents is appropriate. R18-29 PC 4 at 1.³ In addition to the CDC and NIH documents, IHA asked the Board to also consider the “Federal Select Agents and Toxins List,” which IHA characterized as a broader list for the Class 4 etiologic agent category. *Id.* IHA added: “the Illinois regulations that the Board uses in [its] Note are sufficient for this section of the code.” *Id.*

Ultimately, the Board declined to accept either IEPA’s or IHA’s suggestions. The recommended changes would require incorporation by reference of Board Note documents, which would be a substantive change beyond the scope of the rulemaking. Amendments to 35 Ill. Adm. Code Subtitle M: Biological Materials, R18-29, slip op. at 3 (Feb. 14, 2019). However, the Board recognized that substantive consideration of the “Class 4 etiologic agent” definition is necessary, as both IEPA and IHA claimed it was outdated. *Id.* The Board therefore opened a subdocket B (R18-29(B)) to consider any substantive changes. *Id.*

On March 5, 2019, in subdocket B, the hearing officer issued an order inviting comments—by May 6, 2019—on updating the “Class 4 etiologic agent” definition. The order asked whether the Board should incorporate by reference the CDC and BMBL documents or include the Federal Select Agents and Toxins List in the definition of “Class 4 etiologic agent.” The Board received no comments. The hearing officer issued another order on July 17, 2019, seeking comments—by August 9, 2019—on whether the Board should close the subdocket and keep the definition of “Class 4 etiologic agent” without any revision. Again, the Board received no comments. Today, to avoid any potential confusion with docket R18-29, the Board closes subdocket R18-29(B) by separate order and addresses the substance of the definition in this docket, R20-17.

DISCUSSION

Section 56.2(e) of the Act (415 ILCS 5/56.2(e) (2018)) requires that the Board adopt rules that are identical in substance to the listing of Class 4 etiologic agents in “Classification of Etiological Agents on the Basis of Hazard, 1974,” as amended. As discussed below, the Board finds that the 1974 CDC listing of Class 4 etiologic agents was updated by the 2019 NIH

³ The citation refers to PC 4 from docket R18-29. The Board directs the Clerk to enter a copy of that public comment into this R20-17 docket as PC 2.

guidelines, warranting amendments to the Board’s definition of “Class 4 etiologic agent.” Accordingly, the Board proposes those amendments today for public comment.

The NIH guidelines were revised in April 2019.⁴ 84 Fed. Reg. 17858 (Apr. 26, 2019). These 2019 NIH guidelines classify human etiologic agents under four risk groups. “Risk Group 4” consists of agents that “are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.” NIH Guidelines at 48. This risk group is analogous to the 1974 CDC Class 4 etiologic agent definition.

Risk Group 4 of the 2019 NIH guidelines includes all listed 1974 CDC Class 4 etiologic agents except for Alastrim, Small pox, Monkey pox, White pox, Venezuelan equine encephalitis virus, and yellow fever virus. NIH Guidelines at 48. Again, Alastrim, Small pox, and White pox are restricted poxviruses that “may not be studied in the United States except at specified facilities,” while Monkey pox, Venezuelan equine encephalitis virus, and yellow fever virus fall into Risk Group 3. *Id.* at 39, 46, 47. The Board proposes continuing to retain these six viruses in its definition of “Class 4 etiologic agent” when they are used for transmission or animal inoculation experiments. *See id.* at 14 (“[Risk Group 3] agents such as Venezuelan equine encephalomyelitis and yellow fever viruses should be handled at a higher containment level for animal inoculation and transmission experiments.”). In addition, Risk Group 4 also adds Guanarito virus, Sabia, Ebola virus, and Equine Morbillivirus to the 1974 CDC listing of Class 4 etiologic agents. *Id.* at 48. The Board therefore proposes adding these four viral agents to its definition.

Risk groups in the NIH guidelines differ from “biosafety levels” in the CDC/NIH BMBL. Risk groups are “the result of a classification of microbiological agents based on their association with, and resulting severity of, disease in humans.” “Biosafety in Microbiological and Biomedical Laboratories,” 5th Ed., Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health, December 2009 at 24.⁵ On the other hand, in determining the biosafety levels in which work will be conducted, “[t]he risk group of an agent should be *one factor* considered in association with mode of transmission, procedural protocols, experience of staff, and other factors.” *Id.* (emphasis added). As the Board found, due to this elasticity in the BMBL, biosafety levels can vary for a given viral agent based on the laboratory setting and the nature of the experiment. Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, slip op. at 6. Moreover, the most recent CDC/NIH BMBL, 2009, does not assign “Biosafety Level 4” to all viral agents in the Board’s Class 4 definition or the NIH’s Risk Group 4.

⁴ “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines),” Department of Health and Human Services, National Institute of Health, April 2019 (NIH Guidelines).” Available at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

⁵ Available at <https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF>.

The Board proposes updating the list of viral agents in its definition of “Class 4 etiologic agent” by adding the following Risk Group 4 agents from the 2019 NIH guidelines: Guanarito virus; Sabia; Ebola virus; and Equine Morbillivirus.

PUBLIC COMMENT

The Board welcomes public comment on any aspect of the proposed amendments. The Board also specifically requests public comment on the following:

1. Should any other etiologic agents listed in CDC, NIH, or BMBL documents be added to the definition of “class 4 etiologic agent”?
2. Should any agents from the Federal Select Agents and Toxins list be added to the definition of “class 4 etiologic agent”?

Public comments must be filed electronically through the Clerk’s Office On-Line (COOL) on the Board’s website (pcb.illinois.gov). The comment should indicate the docket number for this rulemaking, R20-17. Questions about filing comments can be directed to the Clerk’s Office at 312-814-3461. Public comments and all other filings with the Clerk must be served on the hearing officer and on those persons on the Service List for this rulemaking. The current version of the Service List for R20-17 is available on COOL.

CONCLUSION

For public comment, the Board proposes amendments to the PIMW rules’ definition of “Class 4 etiologic agent.” The Board also directs the Clerk to cause this proposal to be published in the *Illinois Register*. The proposed amendments appear in the addendum to this order; proposed additions are underlined and proposed deletions are stricken through. The Board intends to hold two hearings on the proposal, by videoconference in Chicago and Springfield. See 35 Ill. Adm. Code 101.600(b), 102.114. Interested persons should contact the hearing officer (Chloe.Cummings@Illinois.Gov) to be added to this docket’s Notice List or Service List.

IT IS SO ORDERED.

I, Don A. Brown, Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above opinion and order on December 19, 2019, by a vote of 4-0.



Don A. Brown, Clerk
Illinois Pollution Control Board