The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

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Governor

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Lieutenant Governor

To: Commissioner Monica Bharel and Members of the Public Health Council

From: Carlene Pavlos, Director, Bureau of Community Health and Prevention

Date: June 14, 2017

Re: Informational Briefing on Proposed Amendment to 105 CMR 660.000: *Cigarette and Smokeless Tobacco Products: Reports of Added Constituents and Nicotine Ratings* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Introduction**

The purpose of this memorandum is to inform the Public Health Council of proposed amendments to 105 CMR 660.000, Cigarette and Smokeless Tobacco Products: Reports of Added Constituents and Nicotine Ratings in order to remove the language of the regulation that was deemed unconstitutional by the The U.S. District Court for the District of Massachusetts related to gathering data on added constituents in cigarettes.

105 CMR 660.00 is statutorily required by M.G.L. c. 94, § 307B, which mandates reporting of certain information relating to tobacco products to the Department of Public Health by cigarette manufacturers. The U.S. District Court for the District of Massachusetts struck down the requirement in M.G.L. c. 94, § 307B that tobacco companies disclose all ingredient information as a taking of trade secrets without just compensation in violation of the U.S. Constitution, but upheld the requirement that nicotine content be disclosed. The proposed changes would bring the regulation into accordance with this decision.

**Background**

M.G.L. c. 94, s. 307B, requires tobacco manufacturers to file an annual report concerning nicotine yields with the Massachusetts Department of Public Health (MDPH) for each brand of tobacco product sold in the Commonwealth. This annual report provides nicotine yield ratings which accurately predict nicotine intake for typical consumers, based on standards established by MDPH.

The national standard for testing tar and nicotine by use of a smoking machine was developed over thirty years ago.[[1]](#endnote-1) The nicotine yield ratings produced by this historical method were meant to serve as a relative measure of nicotine yield between cigarette brands.[[2]](#endnote-2)

Cigarette design has undergone significant changes over the last 30 years. Technology has altered the manner in which tar and nicotine are delivered to the smoker, and the smoking practices of consumers have shifted accordingly.Since the introduction of ‘low yield’ cigarettes (i.e., light and ultra-light cigarettes) in the late 1970s, smokers have been found to compensate for lower levels of nicotine yield by smoking more frequently, by smoking more cigarettes, smoking more deeply, and increasing puff volume.[[3]](#endnote-3) These changes in smoking behavior result in much higher relative nicotine levels being delivered to the body from lower yield cigarettes than what is calculated using the historical testing method.[[4]](#endnote-4)

The Family Smoking Prevention and Tobacco Control Act of 2009 gave the FDA authority to require cigarettes companies to disclose ingredient and nicotine levels in cigarettes. However, the FDA does not make this information available to the public. The data collected under the Massachusetts statute is used to inform public health efforts aimed at reducing adverse health effects of use of and exposure to tobacco products. In 2014, a study, led by the Massachusetts Department of Public Health and researchers at UMass Medical School, found that nicotine yield “increased sharply from 1998 to 2012 even as the total amount of nicotine in cigarettes has leveled off.”[[5]](#endnote-5)

**Proposed Amendments**

Proposed amendments to the regulation would remove the language in the regulation that requires ingredient information be disclosed.

**Public Hearing and Comment**

A Public Hearing was held on February 6, 2017. Written comments were accepted through February 10, 2017. No comments were received.

**Summary**

The proposed amendment to 105 CMR 660.00 will bring the regulation into compliance with the U.S. District Court ruling by removing the requirement that tobacco manufacturers disclose all added constituents in cigarettes and smokeless tobacco. It will continue to require disclosure of nicotine yield for use by the Department to inform public health efforts.

Following final action by the PHC, the Department will be able to file the amended regulation with the Secretary of the Commonwealth.

1. Pillsbury, Harold C., Jr. “Review of the Federal Trade Commission Method for Determining Cigarette Tar and Nicotine Yield,” *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 9. [↑](#endnote-ref-1)
2. Peeler, C. Lee. “Cigarette Testing and the Federal Trade Commission: A Historical Overview,” *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 2. [↑](#endnote-ref-2)
3. Zacny, James P. and Maxine L. Stitzer. “Human Smoking Patterns,” *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 154-55. [↑](#endnote-ref-3)
4. Kozlowski, Lynn T. and Janine L. Pillitteri. “Compensation for Nicotine by Smokers of Lower Yield Cigarettes,” *The FTC Cigarette Test for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (Monograph 7)*. Report of the NCI Expert Committee: U.S. Department of Health and Human Services, National Institutes of Health, 168. [↑](#endnote-ref-4)
5. Land T, Keithly L, Kane K, et al. “Recent increases in efficiency in cigarette nicotine delivery: implications for tobacco control,” Nicotine Tob Res 2014; 16:753–8. [↑](#endnote-ref-5)