

105 CMR 660.000 Cigarette and Smokeless Tobacco Products: Reports of Added Constituents and Nicotine Ratings

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660.001: Purpose

The purpose of these regulations is to implement M.G.L. Chapter 94, section 307B, which mandates reporting of certain information relating to tobacco products to the Department of Public Health.

660.002: Authority

These regulations are adopted pursuant to M.G.L. c.94, s. 307B.

660.003: Definitions

As used in 105 CMR 660.000, **et seq.**, the following terms shall have the following meanings, unless the context clearly requires otherwise:

Added Constituent means any ingredient, substance, chemical or compound other than tobacco, water or reconstituted tobacco sheet, which is added by the manufacturer to the tobacco, paper or filter of a cigarette or the tobacco of a smokeless tobacco product during the processing, manufacture, or packing of the cigarette or smokeless tobacco product.

Annual Report means a tobacco manufacturer's annual report to the Department, which provides, for each brand of cigarette and smokeless tobacco product, added constituent information and nicotine yield ratings, as described in 105 CMR 660.100 to 660.103.

Attorney General means the Attorney General of the Commonwealth of Massachusetts.

Cigarette means any product (including components, accessories, or parts) which contains or delivers nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(A) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(B) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filter, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette.

Cigarette Nicotine Yield Rating means a composite of information intended to show the range of nicotine that each cigarette brand can be expected to provide to the average consumer, based on such factors as (1) the expected range of nicotine delivery under average smoking conditions based on machine testing parameters that seek to reflect actual smoking behavior and (2) the potential for increased nicotine delivery or increased speed of nicotine delivery based on cigarette design features such as filter vents, pH, and the total nicotine content of the tobacco.

Commissioner means the Commissioner of the Department of Public Health.

Could Reduce Risks to the Public Health means that knowledge about an added constituent could result in reduced risk of adverse health effects associated with tobacco use, including but not limited to nicotine addiction and adverse health effects associated with exposure to environmental tobacco smoke.

Department means the Department of Public Health.

Federal Trade Commission means the United States Federal Trade Commission.

Manufacturer means any person or entity, including any repacker or relabeler, manufacturing, fabricating, assembling, processing, or labeling a finished cigarette or smokeless tobacco product. The term does not include any person or entity only distributing finished cigarettes or smokeless tobacco products.

Smokeless Tobacco means any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity without burning.

Smokeless Tobacco Nicotine Yield Rating means a composite of information intended to show the range of nicotine that each smokeless tobacco product can be expected to provide to the average consumer, based upon the amount of nicotine in the tobacco, the pH of the tobacco, and the amount of unionized (free) nicotine in the product.

660.100: General Requirements for Annual Reports by Manufacturers

(A) On December 15, 1997, and on every December 1 thereafter, the manufacturer of any cigarette or smokeless tobacco product sold in the Commonwealth as of that date shall report to the Department, in accordance with these regulations, the added constituents and nicotine yield rating of each such cigarette or smokeless tobacco product. To the maximum extent possible, such report shall be submitted electronically to the Department, in accordance with the technical specifications of the Department.

(B) Nothing in this section shall prohibit a manufacturer or distributor of cigarettes or smokeless tobacco products from selling such products to an in-state merchant for sale or distribution outside of the Commonwealth.

660.102: Cigarette Nicotine Yield Rating Reporting Requirements

(A) In each annual report, a manufacturer shall include, as part of the nicotine yield rating for each brand, sub-brand and generic unbranded cigarette, the information specified in section 660.102. For purposes of section 660.102, the term "brand family" shall mean a number of different, though highly similar cigarette products marketed under one general name; e.g. regular, longer-length and menthol cigarettes of the same brand.

For each brand, sub-brand and generic unbranded cigarette which belongs to a brand family that has a national market share of less than 3 percent, as reported in the most recent Maxwell Report, Cigarette Brand Sales and Market Share, published by Davenport and Company, Richmond, Virginia, or a comparable report designated by the Department, the annual report shall include the information specified in subsections 660.102 (B)(1) and 660.102 (B)(6). Said report also shall include the information in subsections 660.102(B)(2), 660.102 (B)(3) and 660.102 (B)(4) for a limited number of individual sub-brands selected by the Department. The number of sub-brands to be selected by the Department shall be based on the manufacturer's national market share, as reported in the most recent Maxwell Report. For a manufacturer with greater than 35 percent of national market share, up to 15 sub-brands shall be selected and tested; for a manufacturer with a national market share of 20 to 35 percent of national market share, up to 9 sub-brands will be selected and tested; and for a manufacturer with a national market share of less than 20 percent, up to 6 sub-brands will be selected and tested.

For each brand, sub-brand and generic unbranded cigarette which belongs to a brand family that has a national market share of 3 percent or more, as reported in the most recent Maxwell Report, Cigarette Brand Sales and Market Share, USA, published by Davenport and Company, Richmond, Virginia, or comparable report designated by the Department, the annual report shall include the information specified in subsections 660.102 (B)(1) through (5).

(B) As specified in section 660.102(A), cigarette manufacturers shall include in their annual report a rating for nicotine yield for each brand, sub-brand and generic unbranded cigarette sold in the Commonwealth, which shall include:

the most recent nicotine level reported for the brand, sub-brand, or generic unbranded cigarette to the Federal Trade Commission, as published in the Federal Trade Commission Report entitled "*Tar, Nicotine, and Carbon Monoxide of the Smoke of Varieties of Domestic Cigarettes*". If no report has been made to the Federal Trade

Commission, the manufacturer shall report the nicotine level determined in accordance with the testing methods specified in subsections 660.500 (A) and (D) (1);
the total nicotine content of the cigarette, reported in milligrams of nicotine and nicotine content per gram of tobacco, as determined under the testing method set forth in 105 CMR 660.500(B);
percent filter ventilation; that is, the level of air dilution in the whole smoke, as provided by the ventilation holes in the cigarette filter, described in percent, as determined under the method described in 105 CMR 660.500(C);
nicotine delivery under average smoking conditions, reported in milligrams of nicotine per cigarette. Manufacturers shall use the Federal Trade Commission testing method, as described and modified in section 105 CMR 660.500(D), with the puff volume adjusted to 45 milliliters, puff interval adjusted to 30 seconds, and puff duration to 2 seconds. The average number of puffs per cigarette taken in this condition shall be reported. Cigarettes with ventilation holes must have the holes half blocked during testing (see 660.500(D) for hole blocking method). Manufacturers shall classify each brand, sub-brand or generic unbranded cigarette for nicotine yield according to the following standards:

Average Cigarette Smoking Conditions

Nicotine Delivery Nicotine (mg/cigarettes)

High Nicotine >1.2 mg

Moderate Nicotine >0.2-1.2

Low Nicotine .01-0.2

Nicotine Free <0.01

Testing and measurement for nicotine yield ratings shall comply with the sampling and conditioning standards set forth in 105 CMR 660.500 (A). The cigarette nicotine yield ratings shall be reported to the Department on the form attached to these regulations as 105 CMR 660.600;

(5) for brand families subject to the requirements of 105 CMR 660.102 (A)(2), the pH of cigarette smoke, as determined under the method specified in 105 CMR 660.500(E), for three sub-brands selected by the Department from each brand family that has a national market share of 3 percent or more, as reported in the most recent Maxwell Report;

(6) for brand families subject to the requirements of 105 CMR 660.102 (A)(1), nicotine level reported in 660.102 (B)(1) multiplied by a numerical factor approved by the Department which is intended to approximate the ratings for nicotine delivery under average smoking conditions which would have been derived by the tests conducted in the preceding year pursuant to section 660.102 (B)(4). The cigarette nicotine yield ratings shall be reported to the Department on the form attached to these regulations as 105 CMR 660.600.

660.103: Smokeless Tobacco Products: Nicotine Yield Reporting Requirements

Smokeless tobacco product manufacturers shall include in their annual report a rating for nicotine yield for each brand, sub-brand or generic unbranded smokeless tobacco product sold in the Commonwealth, which shall include:

pH of tobacco;

moisture content as a percent of weight of tobacco;

nicotine in milligrams per gram of tobacco;

nicotine as a percent of dry weight of tobacco;

percent of unionized (free) nicotine; and

total unionized (free) nicotine in milligrams per gram of tobacco. Smokeless tobacco product manufacturers shall classify each brand, sub-brand and generic unbranded smokeless tobacco product for nicotine delivery, according to the following standard:

Smokeless Tobacco

Total Free Nicotine Delivery mg/g

High Nicotine >2.0

Moderate Nicotine >0.5-2.0

Low Nicotine .01-0.5

Nicotine Free <0.01

The smokeless tobacco nicotine yield rating shall be reported to the Department as specified on the form attached to these regulations as 105 CMR 600.600.

660.300: Severability

If any provisions of 105 CMR 660.000 are held invalid for any reason whatsoever, such declaration shall not effect any other portion of 105 CMR 660.000, which shall remain in full force and effect, and to this end, the provisions of 105 CMR

660.000 **et seq.** are hereby declared severable.

660.500: Testing Methods

(A) **Sampling and Conditioning.** Conditioning for testing of tobacco products shall be done in accordance with the International Organization for Standardization (ISO), 3402, third edition, 1991-07-01 entitled *Tobacco and Tobacco Products -- Atmosphere for Conditioning and Testing*. Cigarettes shall be sampled using international standard ISO §243:98 (E) entitled *Cigarette – Sampling*. At a minimum, for each brand sampled, 35 packages of cigarettes shall be purchased from a Massachusetts wholesaler at a single point in time. Ten of these packs shall be mailed or delivered to the Department of Public Health. Smokeless tobacco products will follow the sampling protocol outlined in "Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products".

(B) **Total Nicotine Content.** The protocol for measuring nicotine content in cigarette and smokeless tobacco products and for moisture content and pH in smokeless tobacco products is described in "Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless tobacco Products" (or most recent amended version), announced in the Federal Register of May 2, 1997, volume 62, no. 85, pp. 24115-24116. In measuring nicotine content, the cigarette manufacturer shall use the following sampling method: two cigarettes shall be randomly selected from each pack and conditioned, the tobacco rod split open, and the cigarette tobacco mixed thoroughly before weighing. The minimum sample size shall be 100 grams of tobacco. If the weight of the tobacco is less than 100 grams, additional cigarettes shall be randomly selected from each pack.

(C) **Percent Filter Tip Ventilation** means the level of air dilution in the whole smoke, as provided by the perforations made in the cigarette filter tip, described in percent. This shall be measured using the Filter Dilution (Ventilation) Testing Instrument (FDT) from Fidus Instrument Corporation, product no. FDT 232; or FIAL Tip and Envelope Ventilation/Pressure Drop QTM5U machine; or equal approved by the Department, and shall be used in accordance with manufacturer instructions. Two cigarettes shall be randomly selected from each sampled pack, conditioned, and tested for percent filter ventilation. The average percent filter ventilation shall be computed for the 100 cigarettes tested.

(D) Modified FTC Testing Method.

Nicotine delivery under average smoking conditions shall be evaluated using the Cambridge Method, which has been approved by the Federal Trade Commission (FTC) as the standard for nicotine testing since 1966, and adopted for international purposes by the ISO. See Federal Register, Vol. 32, No.147, page 11178, dated August 1, 1967, as modified by the FTC in Federal Register, Vol. 45 No. 134, pages 46483-46487, dated July 10, 1980; ISO 10315, 91-08-01 entitled "Cigarettes-Determination of Nicotine in Smoke Condensates-Gas-Chromatographic Method"; ISO 3308, third edition, 1991-10-15, "Routine Analytical Cigarette-Smoking Machine - Definition of Standard Conditions"; and ISO 7201, second edition, 1997-01-15, "Routine Analytical Smoking Machine Additional Test Methods". Two cigarettes shall be randomly selected from each pack for a sample of 50 cigarettes.

The Department has modified the FTC and ISO conditions to require the following changes to the testing method:

Puff volume as prescribed in the FTC method and in the ISO 3308: 4.3 shall be increased from 35 ml to 45 ml;
Puff frequency as prescribed in the FTC method and ISO 3308: 4.4 shall be changed from one puff each minute to one puff every 30 seconds;

Puff duration shall remain at two seconds;

50% of the ventilation holes must be blocked by placing a strip of mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape (Acetate) or other method approved by the Department. The tape shall be cut so that it covers 50% of the circumference and is tightly secured from the end of the filter to the tipping overwrap seam;

Number of cigarettes smoked per port shall be three, provided that the limit of 150 milligrams of tar is not exceeded (see ISO 4387).

(E) **pH Testing Method.** Testing for pH shall be conducted on a puff by puff basis, in accordance with the testing method described in Sensabough, A. J., Jr. and Candiff, R.H., "A New Technique for Determining the pH of Whole Tobacco Smoke", Tob.Sci. , 11: 25-30 (1967) and Brunnemann, K.D. and Hoffman, D., "The pH of Tobacco Smoke", Food, Cosmet. Toxicol. , 112:115 (1974), or comparable testing method approved by the Department.

660.600: Cigarette Nicotine Yield Rating Form

(1) Brand _____ Sub-Brand _____

(2) Most Recent Nicotine Level Reported to the FTC _____

(3) Total Nicotine Content in Cigarette Tobacco (Milligrams) _____

Nicotine: mg/g of tobacco _____

(4) pH of Smoke _____ Percent Filter Ventilation _____

(5) Nicotine Delivery Under Average Smoking Conditions _____

(6) Classification _____ Number of Puffs _____

(> 1.2milligrams:high; > 0.2-1.2:moderate; .01-0.2:low; < .01: nicotine free)

(7) pH _____

Puff 1 2 3 4 5 6 7 8 9 10 11 12 13 Mean

Smokeless Tobacco Nicotine Yield Rating Form

(1) Brand _____ Sub-Brand _____

(2) Moisture Content in Percent _____ Nicotine as a Percent of Dry Weight Tobacco _____

(3) Nicotine in Milligrams per Gram of Tobacco _____

(4) pH _____

(5) Total Unionized (free) Nicotine _____

(6) Classification _____

(> 2.0 milligrams:high; > 0.5-2.0:moderate; 0.1-0.5:low; < 0.01: nicotine free)