

WikiLeaks Document Release

 $\begin{array}{c} \text{http://wikileaks.org/wiki/CRS-RS22944} \\ \text{February 2, 2009} \end{array}$

Congressional Research Service

Report RS22944

Federal Trade Commission Guidance Regarding Tar and Nicotine Yields in Cigarettes

Vanessa K. Burrows, American Law Division

Updated September 4, 2008

Abstract. In 1966, the Federal Trade Commission (FTC or Commission) stated that a cigarette test methodology known as the Cambridge Filter Method or FTC Test Method was the methodology "to be used to support any factual statements of tar and nicotine content of the mainstream smoke of cigarettes." The FTC statement did not mandate that cigarette companies state tar and nicotine yields on tobacco product packaging, but rather determined "the type of substantiation the Commission would deem adequate to support statements of tar and nicotine yields if cigarette companies choose to make such statements." Recently, the FTC issued a notice in the Federal Register that proposed to rescind this statement, reasoning that because the cigarette test method has "serious limitations," the FTC's allowance of factual statements regarding tar and nicotine based on the Cambridge Filter Method "may be confusing or misleading to consumers who believe they will get proportionately less of the harmful substances from cigarette smoke by smoking relatively lower-yield cigarettes." This report discusses the test method and the FTC's initial statement, implications of rescinding the FTC's guidance statement, and provisions in H.R. 1108, S. 625, and S. 2685.





Federal Trade Commission Guidance Regarding Tar and Nicotine Yields in Cigarettes

Vanessa K. Burrows Legislative Attorney American Law Division

Summary

In 1966, the Federal Trade Commission (FTC or Commission) stated that a cigarette test methodology known as the Cambridge Filter Method or FTC Test Method was the methodology "to be used to support any factual statements of tar and nicotine content of the mainstream smoke of cigarettes." The FTC statement did not mandate that cigarette companies state tar and nicotine yields on tobacco product packaging, but rather determined "the type of substantiation the Commission would deem adequate to support statements of tar and nicotine yields *if* cigarette companies choose to make such statements." Recently, the FTC issued a notice in the *Federal Register* that proposed to rescind this statement, reasoning that because the cigarette test method has "serious limitations," the FTC's allowance of factual statements regarding tar and nicotine based on the Cambridge Filter Method "may be confusing or misleading to consumers who believe they will get proportionately less of the harmful substances from cigarette smoke by smoking relatively lower-yield cigarettes." This report discusses the test method and the FTC's initial statement, implications of rescinding the FTC's guidance statement, and provisions in H.R. 1108, S. 625, and S. 2685.

The Cambridge Filter or FTC Test Method. The cigarette industry uses a test methodology initially set forth by the Federal Trade Commission in 1967 to determine tar and nicotine ratings of cigarettes. This method, which relies on the use of a machine "to produce uniform, standardized data about the tar and nicotine yields of mainstream

¹ Press Release, Federal Trade Commission, FTC to Begin Cigarette Testing (Aug. 1, 1967), [http://www.philipmorrisusa.com/en/cms/Products/Cigarettes/Tar_Nicotine/ftc_1967_press_release.aspx]. Prior to the use of the Cambridge Filter Method, cigarette manufacturers used different testing methods to determine tar and nicotine yields, "making cross-brand comparison unreliable." Price v. Philip Morris, Inc., 848 N.E.2d 1 (Ill. 2005), 2005 Ill. LEXIS 2071, at *4. In 1955, the FTC allowed industry manufacturers to make such claims "only if they could substantiate their claims by 'competent scientific proof.'" *Id.* at *3.

cigarette smoke," is known as the FTC Test Method or the Cambridge Filter Method.² Under the Cambridge Filter Method, a machine "take[s] one puff of 2-second duration and a 35ml volume every minute" and smokes each cigarette "to a specified length."³ According to the agency, this testing method is not intended "to replicate actual human smoking." The machine measures tar, nicotine, and carbon monoxide yields of the different cigarette brands.⁵ Cigarettes with a tar rating above 15 mg. are commonly referred to by the industry as "full flavor." Cigarettes with a tar rating of less than 15 mg. are referred to by the industry as "low" or "light," while cigarettes with a tar rating of 6 mg. or less are referred to by the industry as "ultra low" or "ultra light." These descriptive terms that the industry uses are not defined by the FTC or the government in general, as the United States stated in an amicus brief to the Supreme Court. However, an expert witness for Philip Morris has asserted, in *Price v. Philip Morris, Inc.*, discussed below, that the FTC has given guidance to the industry "and others regarding the use of descriptors" such as "low tar" in two FTC consent orders between the FTC and the American Brands cigarette company, from 1971 and 1995, as well as in FTC reports to Congress and other agency documents.⁸

The FTC has expressed concerns that the tar and nicotine ratings based on the machine test method "tend to be relatively poor predictors of tar and nicotine exposure," as smokers of cigarettes with lower tar or nicotine ratings (i.e., "light" and "ultra low" cigarettes) tend to compensate by "tak[ing] bigger, deeper, or more frequent puffs, or otherwise alter[ing] their smoking behavior to obtain the dosage of nicotine they need." Such compensation may thus affect "the amount of tar, nicotine, and carbon monoxide

² Accuracy of the FTC Tar and Nicotine Cigarette Rating System Before the Senate Comm. on Commerce, Science, and Transportation, 110th Cong. (Nov. 13, 2007) (statement of William E. Kovacic, FTC Commissioner), at 1-2, 6, available at [http://commerce.senate.gov/public/_files/Kovacic_P064508CommissionTestimonyReTobaccoAdvertisingSenate11132007.pdf]. [Hearinafter Kovacic].

³ *Id.* at 6-7.

⁴ *Id.* at 2.

⁵ *Id.* at 5.

⁶ *Id.* at 6, n. 16.

⁷ Brief for the United States as Amicus Curiae, Watson v. Philip Morris Companies, Inc., 551 U.S. __ (2007) (No. 05-1284), 2005 U.S. Briefs 1284, at *4, *21.

⁸ Kovacic, *supra* note 2, at 6; *see* Philip Morris USA, Inc. v. Byron, 876 N.E.2d 645, 646 (Ill. 2007) (Freeman, J., dissenting); *see also* Price v. Philip Morris, Inc., 848 N.E. 2d 1 (Ill. 2005); 2005 Ill. LEXIS 2071, at *16, *20, *25-*26, *60, *64 (describing a letter from the FTC to the Code Authority of the National Association of Broadcasters that stated "the use of 'low' and 'less' or similar words when describing tar and nicotine content, creates an imprecise picture, which, absent a full and fair disclosure, could lead to a mistaken conclusion that the advertised brand is lower in tar and nicotine than many other brands").

⁹ Kovacic, *supra* note 2, at 7; 73 Fed. Reg. 40351. "Prior to the adoption of the 1984 revisions [to cigarette warning labels], both the FTC and the Surgeon General recommended to Congress that the required warnings address the phenomenon of compensation This recommendation was not adopted." Price v. Philip Morris, Inc., 848 N.E. 2d 1 (Ill. 2005); 2005 Ill. LEXIS 2071, at *7.

they get from any particular cigarette."¹⁰ Additionally, a report by the National Cancer Institute found that, as a result of such compensation, "the current U.S. cigarette tar and nicotine yields as measured by the FTC method [are] not useful to the smoker either for understanding how much tar and nicotine he or she is likely to inhale from smoking a given cigarette or for comparing the tar and nicotine intake that is likely to result from smoking different brands."¹¹ Some tobacco companies acknowledge that there may be a difference between tar and nicotine ratings per the FTC method and the actual amount that smokers receive.¹²

The FTC 1966 Guidance and the Agency's Proposal to Rescind It. In a 1966 Federal Register notice of public hearing, the FTC stated that the Cambridge Filter Method "was specified by the Commission on March 25, 1966, as that to be used to support any factual statements of tar and nicotine content of the mainstream smoke of cigarettes." The March 25, 1966 statement by the FTC did not mandate that cigarette companies state tar and nicotine yields on tobacco product packaging, but rather "set[] forth the type of substantiation [the Cambridge Filter Method] the Commission would deem adequate to support statements of tar and nicotine yields *if* cigarette companies choose to make such statements." This 1966 guidance indicated that such factual statements "generally will not violate the FTC Act," as long as

(1) no collateral representations (other than factual statements of tar and nicotine content of cigarettes offered for sale to the public) are made, expressly or by implication, as to reduction or elimination of health hazards, and (2) the statement of tar and nicotine content is supported by adequate records of tests conducted in accordance with the Cambridge Filter Method.¹⁵

On July 14, 2008, the FTC issued a notice in the *Federal Register* that proposed to rescind its March 25, 1966 statement. The Commission reasoned that because the Cambridge Filter Method has "serious limitations," the FTC's allowance of factual statements regarding tar and nicotine based on the Cambridge Filter Method "may be

¹⁰ Kovacic, *supra* note 2, at 7.

¹¹ *Id.* at 10 (quoting National Institutes of Health, National Cancer Institute, *Smoking and Tobacco Control Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine* (Nov. 2001), at 34).

¹² The "Official Website for Camel Cigarettes" includes a disclaimer after listing its tar and nicotine ratings for various brands that states, "Actual amount may vary depending on how you smoke." Official Website for Camel Cigarettes, [http://www.smokerswelcome.com/CAM/dtclogin.jsp?brand=CAM]. Philip Morris USA cigarette brands contain the statement: "The amount of 'tar' and nicotine you inhale will vary depending on how you smoke the cigarette." Philip Morris USA, Cigarettes, Understanding Tar & Nicotine Numbers, [http://www.pmusa.com/en/cms/Products/Cigarettes/Tar_Nicotine/default.aspx?src=top_nav].

¹³ Cigarettes and Related Matters: Methods To Be Employed in Determining Tar and Nicotine Content; Notice of Public Hearing, 31 Fed. Reg. 14278 (Nov. 4, 1966).

¹⁴ Proposal to Rescind FTC Guidance Concerning the Current Cigarette Test Method, 73 Fed. Reg. 40350, 40351 (July 14, 2008).

^{15 73} Fed. Reg. 40351.

¹⁶ 73 Fed. Reg. 40350.

confusing or misleading to consumers who believe they will get proportionately less of the harmful substances from cigarette smoke by smoking relatively lower-yield cigarettes." The FTC also stated that its initial rationale for permitting such statements — a belief in 1966 "that reducing the amount of 'tar' in a cigarette could reduce a smoker's risk of lung cancer," and therefore that providing information about tar and nicotine yields could aid smokers in "mak[ing] informed decisions about the cigarettes they smoked" — "no longer appears valid." "18

Implications of Rescission. If the agency rescinds its guidance, the cigarette industry "should no longer use terms suggesting the FTC's endorsement or approval of any specific test method." Phrases that would need to be withdrawn if the guidance is rescinded would include terms such as "per FTC method." For example, the "Official Website for Camel Cigarettes" lists several brands of Camel cigarettes, as well as their tar and nicotine average ratings "per cigarette by FTC method." The FTC stated that its proposal to rescind the guidance did not address the use of descriptive terms such as "low" or "ultra light," because the agency has not provided guidance regarding, authorized the use of, or created an enforcement policy with respect to such descriptors.²² However, the FTC stated that once it rescinds the guidance on factual statements regarding tar and nicotine, such statements "would be evaluated the same as any other advertising or marketing claims subject to the Commission's jurisdiction: the statements could be made as long as they were truthful, non-misleading, and adequately substantiated."²³ Since the FTC noted in its proposal to rescind the guidance that statements based on the Cambridge Filter Method "may be confusing or misleading to consumers," the rescission of this guidance may lead to FTC enforcement actions in the future.²⁴

Does the FTC Need to Even Propose to Rescind Its 1966 Guidance?

The proposal to rescind the FTC's March 25, 1966 news release states that the press release is a guidance document. A guidance document is a type of a general statement of policy under the Administrative Procedure Act (APA).²⁵ General statements of policy are

¹⁷ 73 Fed. Reg. 40352.

¹⁸ 73 Fed. Reg. 40351-52.

¹⁹ Press Release, FTC, FTC Proposes Rescinding a 40-Year Guidance on Statements Concerning Tar and Nicotine Yields (July 8, 2008), [http://www.ftc.gov/opa/2008/07/cigarettefyi.shtm]; 73 Fed. Reg. 40352.

²⁰ 73 Fed. Reg. 40351.

²¹ Official Website for Camel Cigarettes, [http://www.smokerswelcome.com/CAM/dtclogin.jsp?brand=CAM].

²² 73 Fed. Reg. 40352.

²³ 73 Fed. Reg. 40352.

²⁴ 73 Fed. Reg. 40352.

²⁵ Executive Order 13422 defines a guidance document as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue." (continued...)

"statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." In this case, the FTC advised the cigarette industry as to how it would address factual statements based on the Cambridge Filter Method. Guidance documents do not "impose any rights and obligations," nor do they "establish a 'binding norm' because they are "not finally determinative of the issues or rights to which [they are] addressed." ²⁸

The APA's procedural requirements regarding notice-and-comment rulemaking do not apply to "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." Therefore, while a notice in the *Federal Register* would be required to repeal a rule, there is no similar requirement for the withdrawal of a guidance document. However, it appears that the FTC is publishing a notice of its proposal to withdraw the guidance document in the *Federal Register* for the sake of clarifying agency policy and, perhaps, as a matter of good governance, as the rescission of the guidance may be controversial and have consequences for the cigarette industry. ³¹

Select Court Cases. In *Price v. Philip Morris, Inc.*, the Illinois Supreme Court partly relied on the FTC's guidance document, in conjunction with consent orders and other statements by the agency, in determining that a cigarette company could not be held liable for light and low-tar labeling under a state consumer fraud statute. In the court's view, the FTC "specifically authorized" tobacco companies' use of such terms if they were "accompanied by a clear and conspicuous disclosure of the 'tar' and nicotine

[http://www.whitehouse.gov/news/releases/2007/01/20070118.html].

²⁵ (...continued)

²⁶ Tom C. Clark, Attorney General, Attorney General's Manual on the Administrative Procedure Act, at 30 n.3 (1947), [http://www.law.fsu.edu/library/admin/1947iii.html] [hereinafter AG Manual]; *see*, *e.g.*, Chamber of Commerce v. United States Department of Labor, 174 F.3d 206, 212 (D.C. Cir. 1999) ("In *American Bus Association v. United States*, we held that the question whether a rule is a policy statement is to be determined by whether it (1) has only a prospective effect, and (2) leaves agency decisionmakers free to exercise their informed discretion in individual cases.") (internal citations omitted).

²⁷ Community Nutrition Institute v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (internal quotations omitted).

²⁸ Pacific Gas & Electric Co. v. Federal Power Commission, 506 F.2d 33 (D.C. Cir. 1974).

²⁹ 5 U.S.C. § 553(b).

³⁰ 5 U.S.C. § 552(a)(1)(E).

³¹ The Office of Management and Budget's (OMB) Final Bulletin for Agency Good Guidance Practices encourages agencies to "consider observing notice-and-comment procedures for interpretive significant guidance documents that effectively would extend the scope of the jurisdiction the agency will exercise, [or] alter the obligations or liabilities of private parties." Executive Office of the President, OMB, Final Bulletin for Agency Good Guidance Practices, at 15, [http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf]. It does not appear that the March 25, 1966 FTC guidance is a significant guidance document. Executive Order 13422 defines a "significant" guidance document, [http://www.whitehouse.gov/news/releases/2007/01/20070118.html].

content."³² This fall the United States Supreme Court will hear the case *Altria Group v. Good*, which will determine whether challenges under state deceptive trade practices laws "to FTC-authorized statements regarding tar and nicotine yields in cigarette advertising are expressly or impliedly preempted by federal law."³³

Proposed Legislation. Legislation that would authorize the Food and Drug Administration (FDA) to regulate tobacco, H.R. 1108/S. 625, the Family Smoking Prevention and Tobacco Control Act, would address tar and nicotine yield issues. H.R. 1108/S. 625 would require the FDA to conduct a rulemaking to determine whether tar and nicotine yields must be included on cigarette advertisements and labeling. H.R. 1108/S. 625 would also authorize the FDA to establish a new testing methodology. Differences between a new FDA method and the FTC's "tar and nicotine yield reporting requirements" would be "resolved by a memorandum of understanding" between the two agencies.³⁴ Additionally, Senator Lautenberg has introduced legislation, S. 2685, the Truth in Cigarette Labeling Act of 2008, which would prohibit cigarette manufacturers from "mak[ing] any claims or other representations based on data derived from a cigarette testing method established by" the FTC.³⁵

³² See Philip Morris USA, Inc. v. Bryon, 876 N.E.2d 645 (Ill. 2007); Price v. Philip Morris, Inc., 848 N.E. 2d 1 (Ill. 2005); 2005 Ill. LEXIS 2071, at *134.

³³ Good v. Altria Group, Inc., 501 F.3d 29 (1st Cir. 2007), *cert. granted* (U.S. Jan. 18, 2008) (No. 07-562), [http://origin.www.supremecourtus.gov/qp/07-00562qp.pdf].

³⁴ H.R. 1108, § 206; S. 625, § 206.

³⁵ S. 2685, § 2(c).