# Comment
# Cigarette Test Method [P944509]

## FEDERAL TRADE COMMISSION

Proposal to Rescind FTC Guidance Concerning the Current Cigarette Test Method

Dear Sir or Madam,

With respect to the questions asked by Commission requesting a response:

**Question 1.**

**Should the Commission rescind its guidance that generally permits factual statements about tar and nicotine when such statements are based on a single standardized test method, the Cambridge Filter Method?**

**Question 2**

**What effects, if any, would the Commission's proposal likely have on consumers' purchases of cigarettes and/or their smoking behavior? Will these changes be likely to affect smoking intensity, brand choice, and/or the decision whether to quit smoking, and if so, how? How else would the proposal likely affect consumers?**

**Response:**

- **The Commission should <u>not</u> rescind its guidance.**

- **The Commission should amend its guidance to incorporate new knowledge relating to the effects of smoking topography and the levels of various toxins in cigarette smoke. Any such changes should be compatible with measures for tobacco products other than cigarettes.**

- **Simply rescinding the current FTC method and putting nothing in its place will confuse and frustrate adult smokers who are aware of the health consequences of continuing to smoke, and who seek information on how to assess their risk.**

- **Rescinding the method and putting nothing in its place will lower the confidence of the public in the government and the public health community.**

Cigarette companies have listed tar, nicotine and carbon monoxide levels using the FTC method for forty-two years. In that time the "tar and nicotine" numbers have become a competitive issue in cigarette marketing. While epidemiological studies have generally found a modest health advantage to lower "tar" cigarettes, studies of biomarkers of

nicotine and toxin absorption have not shown low tar and nicotine cigarettes to be delivering significantly less toxins.[1]

Simply put, smokers will smoke "low nicotine" cigarettes using compensatory methods to increase the nicotine yield beyond what is collected by the machine method. This has led some public health advocates to consider the listing  and advertising of FTC tar and nicotine levels as false and misleading, and to recommend that the guidance be withdrawn to prevent the public from being misled (by concluding that low-tar cigarettes are safer products).

Withdrawing the FTC method is not the solution to this issue.

However well-intentioned the motive, (to stop misleading advertising), the effect will be to:

1. Remove the incentive to measure tar, nicotine and other toxins.

2. Remove the incentive to reduce the toxicity of  cigarettes.

3. Reduce the information available to the public without providing new facts that reflect new knowledge.

Under this proposal a manufacturer who had actually made a reduced-exposure cigarette would not be allowed to say so, while a manufacturer who made a more toxic product would be protected.

This is hardly good regulatory practice or in the public interest.

**The better alternative is to FIX THE FTC METHOD.**

**We have been here before-** The nature of regulatory standards and methods is that they are made under conditions of imperfect knowledge, initially do great good, but tend to become less relevant and an end to themselves, as industry manufactures a product to "meet the rule". All laboratory and product standards tend to become stale with time and need periodic revision.

For example, in 1966 it seemed reasonable to measure tar, nicotine and carbon monoxide. This had the effect of rapidly driving the consumer toward filter cigarettes, and the available data clearly supports filter cigarettes as having lower toxicity than unfiltered cigarettes.

By 2000, it was clear that low tar products were not "better" or "safer" than conventional filter cigarettes, and that smokers were smoking the "low tar" products in ways that might actually increase their risk, in order to get adequate nicotine delivery.

This tells us that we should **fix the method for reporting on various toxins in cigarettes.**

**Fixing the FTC method-** To repair the FTC method, cigarettes must be viewed as a nicotine delivery device. The function of the cigarette is to deliver nicotine adsorbed on a smoke particle to the lungs. Thus, the standard of quality for the cigarette as a product is how well it delivers nicotine, and how contaminated the nicotine is upon delivery.

For the purposes of this discussion, a reduced-exposure product would deliver fewer associated toxins per milligram of delivered nicotine.

Taking the 1994 FTC monograph data on tar and nicotine we can look at the tar expressed per milligram of nicotine. When we look at the relationship between machine yields of tar and nicotine, we see that the relationship is nearly a straight line. Therefore, it is not surprising that if smokers "smoke to a desired nicotine delivery" of about 1 mg of nicotine per cigarette, there would be minimal differences in health outcomes for these products **when characterized as milligrams per cigarette, uncorrected for nicotine delivery.**

**Bivariate Fit of Tar By Nicotine (1994 dataset)**
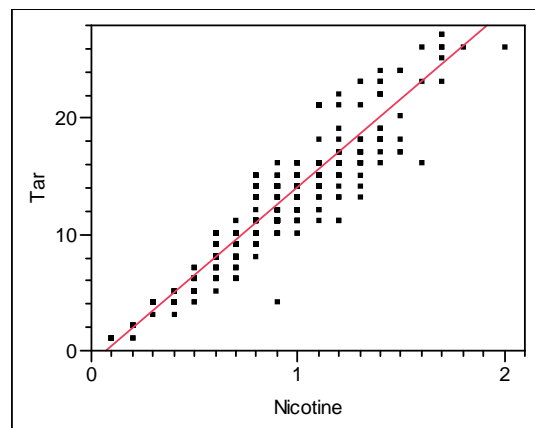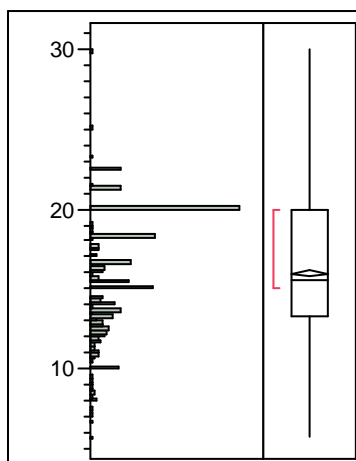
Looking at Tar expressed per milligram nicotine:

**TAR/mg nicotine**
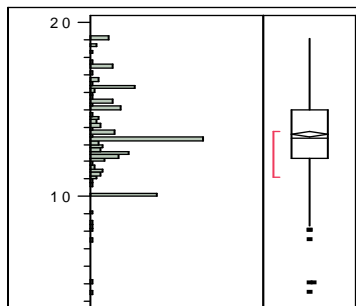


**Quantiles**

| | | |
|---|---|---|
| 100.0% | maximum | 19.091 |
| 99.5% | | 19.091 |
| 97.5% | | 19.091 |
| 90.0% | | 16.667 |
| 75.0% | quartile | 15.000 |
| 50.0% | median | 13.333 |
| 25.0% | quartile | 12.222 |
| 10.0% | | 10.000 |
| 2.5% | | 10.000 |
| 0.5% | | 8.000 |
| 0.0% | minimum | 4.444 |

Looking at carbon monoxide the same way:

**CO/mg nicotine**



**Quantiles**

| | | |
|---|---|---|
| 100.0% | maximum | 30.000 |
| 99.5% | | 22.500 |
| 97.5% | | 22.500 |
| 90.0% | | 20.000 |
| 75.0% | quartile | 20.000 |
| 50.0% | median | 15.556 |
| 25.0% | quartile | 13.333 |
| 10.0% | | 11.111 |
| 2.5% | | 8.571 |
| 0.5% | | 7.143 |
| 0.0% | minimum | 5.714 |

When the cigarette is visualized as a nicotine delivery system, with tar and carbon monoxide as undesirable impurities or contaminants, there is a 5-6 fold range of differences in the amount of tar or CO per milligram of nicotine. There is a clear difference between the products delivering 19 mg of tar or 30 mg of carbon monoxide for every milligram of nicotine, and those delivering 4 mg of tar and 5 mg of carbon monoxide per mg of nicotine.

Expressing contaminants per milligram of nicotine delivered favors the product which delivers the least tar and the minimum CO per milligram of nicotine. Ingestion of the lowest amount of avoidable toxic contaminants should be the regulatory goal for any consumer product.

**Recommendations**

The FTC (Cambridge) method needs some small changes to incorporate new knowledge. The filter seal needs to be lengthened to approximate occlusion of vent holes by real human lips, the puff volume needs to be increased and the butt length reduced for low-tar cigarettes . These are minor changes which can be accomplished by updating the standard methods to accommodate what has been learned about the smoking topography of low and ultra-low tar products. Reports available on the Internet indicate that this has already been done for "Now', "Eclipse" and Carlton". Any of the commercial laboratories doing this work can advise the agency.

More importantly, it is past time that the known toxins in cigarette smoke get space on the label, expressed per milligram of delivered nicotine, and that similar disclosure be required for all tobacco products. We may not know everything about tobacco toxicity, but the millions spent on smoking research in the last 40 years has given us certain knowledge of the major toxins in cigarette smoke.

The amount of nicotine delivered by the cigarette (mg per cigarette) is a content measure ( i.e., pound of lard, peck of apples) and should be listed on the package as with any other consumer product.

Research has clearly delineated the risk, and good commercial test methods are available for:

1. Tar (mg per milligram of delivered nicotine)

2. Carbon monoxide (mg per milligram of delivered nicotine)

3. Aldehydes (acetaldehyde, crotonaldehyde and formaldehyde) micrograms per milligram of delivered nicotine

4. Benzo[a]pyrene (nanograms per milligram nicotine)

5. Tobacco specific nitrosamines (micrograms per milligram nicotine)

Critics will raise the concern that the levels of these toxins have not yet been shown to be definitively predictive of risk. The "precautionary principle", well established in environmental law, makes clear that it is not necessary to wait for full scientific certainty to require that the level of toxic contaminants in a consumer product be reduced to the lowest practical level. There is ample evidence that these compounds are toxic and/or carcinogenic and avoiding them is in anyone's best interest.

## Conclusion and Rationale

Simply abandoning the FTC method and stripping the data from cigarette packages will send the wrong message and may be viewed by the public as a major victory by the cigarette industry.

It is much better policy to recognize that it is time to fix the methods and use the opportunity to get some more useful information on the packages.

This can be accomplished by amending the original text to the following:

**so long as: (1) no collateral representations (other then factual statements of tar, nicotine and toxin contents of cigarettes offered for sale to the public) are made, expressly or by implication, as to the reduction or elimination of health hazards, (2) the statement of tar, toxin and nicotine content is supported by adequate records of tests conducted in accordance with the Cambridge Filter Method as modified in 2008, and (3) results for known cigarette toxins (tar, carbon monoxide, aldehydes, benzo[a]pyrene and tobacco specific nitrosamines) are included, expressed per milligram of delivered nicotine.**

Such a modification will enable the consumer to make choices which might lower their risk or (if no such products exist) to remove the incentive for deceptive promotion. Most importantly, it also will act as an incentive to the cigarette industry to reduce toxic contaminants to the lowest practical level, and makes sure that there is an impetus for similar disclosure on the toxins in other tobacco products.

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1. Risks Associated with Smoking Cigarettes with Low Machine- Measured Yields of Tar and Nicotine, 2001, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Public Health Service National Institutes of Health, National Cancer Institute MONOGRAPH.