

BEFORE THE FEDERAL TRADE COMMISSION

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CIGARETTES AND RELATED MATTERS

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METHODS TO BE EMPLOYED IN DETERMINING CO,  
"TAR" AND NICOTINE CONTENT

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COMMENTS IN RESPONSE TO THE FEDERAL REGISTER  
NOTICE OF JANUARY 18, 1979

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The following comments in response to the Commission's Notice of January 18, 1979 (44 Federal Register 3777) are submitted on behalf of six companies: American Brands, Inc., Brown & Williamson Tobacco Corporation, Liggett & Myers Tobacco Company, Inc., Lorillard, Philip Morris, Inc., and R. J. Reynolds Tobacco Company.

The Federal Register announcement invited comments as to three specific questions. Before turning to those questions, there are two preliminary observations which must be made.

First, the undersigned wish to emphasize that a number of eminent scientists are of the view that cigarette smoking has not been scientifically established as causing the diseases or conditions in human beings which have been associated with cigarette smoking. Further, there is no ingredient or ingredients as found in cigarette smoke which have been shown to produce such diseases or conditions. The testing for and publication of CO content by the Commission will, in the companies' view, imply to consumers without scientific proof that CO content has relevance or significance in terms of health.

Second, the undersigned wish to set forth in the record the fact that the Commission has not honored or adhered to the procedures which it promised to follow in connection with the

development of the methodology for the determination of CO content. Specifically, in a letter dated March 14, 1977, Russell Hatchl, a Commission official, wrote to counsel for the undersigned stating that:

"We realize that the new machine will have to be tested for 'tar' and nicotine and the results compared with the old machine, and that CO in cigarette smoke will have to be tested with other laboratories which have had experience with determining CO by other methods as well. After these tests are completed, and only then, can the methodology be finalized and reduced to writing. At this time a collaborative study will be conducted to determine how well the method works in other laboratories with experienced and inexperienced people running the test. After a successful collaborative test we will write the method which will be used by the Commission's laboratory."

The Commission simply has not followed the approach outlined by Mr. Hatchl. It is our understanding that the Commission reduced to writing its methodology without running tests in conjunction with other laboratories which have had experience in determining CO by other methods as well. Nor is there any suggestion as to the conduct of the collaborative study promised by Mr. Hatchl. The Commission's failure to honor its commitment in this regard is not merely a procedural matter. Unless procedures of this type have been complied with, the Commission's methodology cannot have an adequate scientific basis and should not be considered for or used in obtaining results which will be disseminated to the public.

With these general observations in mind, the undersigned now address the three specific inquiries posed by the Federal Register announcement.

A. Should the Commission Laboratory, In Performing A CO Analysis, Use The "New Smoking Machine" Described In The Paper By Messrs. Merfeld And Pillsbury?

On the basis of the information made available by the Commission the answer to this first question is clearly "no," i.e., the Commission should not use the smoking machine described by Merfeld and Pillsbury to conduct CO determinations.

There are a number of separate and wholly-independent reasons which lead to this conclusion.

FIRST, there are no published data obtained from smoking cigarettes on this machine, which establish that this machine yields accurate and reproducible results.

The Commission has not even published any data on the machine's performance. How could any scientist possibly agree that this machine could be used without documentation or that it performs satisfactorily? The absence of data is particularly significant here because this smoking machine represents a radical departure in design from smoking machines which are used throughout the world and which have proven themselves to be acceptable through long experience.

What the Commission has supplied thus far is merely a description of the physical appearance of the machine and its mechanical operating principles. This provides little or no basis for concluding that its operating capability, reliability, accuracy or precision are satisfactory. These attributes can only be evaluated by close examination of significant quantities

of experimental data generated by use of the machine.

This insistence upon actual data from the machine is not mere procedural haggling. There are numerous possible or probable sources of error in CO measurement associated with this design and the proposed analytical method. These include, for example, the cumulative error due to the analysis of the individual puff, the effect of "dead volume" associated with the gas transport tubing, the response time and accuracy of the non-dispersive analyzer, and the precision associated with the data analysis equipment. In the "tar" and nicotine determinations, it remains to be seen whether or not the new machine will produce data comparable to the machine used in the presently accepted procedure. Small differences in puffing profiles, in cigarette holding techniques, and in butt length determination, as well as the necessity to draw clearing puffs of room air after each cigarette could contribute to differences in "tar" and/or nicotine values from those which would be derived from the standard machine. No data upon which to judge the presence, absence or significance of these differences have as yet been made public.

Moreover, what is required, before it could be agreed that the Commission's machine is satisfactory, are not merely data obtained from smoking on that machine. Rather the performance of this machine should be checked against machines and methods that are known to work acceptably. This should be done with

well-defined cigarette samples in a cooperative test involving several different laboratories.

It will be recalled that in the case of "tar" and nicotine testing, a collaborative study had been done on the method involved before it was even proposed by the Commission. That is the only way one can pass judgment on the acceptability of such new technology. We are deciding issues in the realm of analytical chemistry, and in this field it is standard procedure cooperatively to check out new technology before it is accepted. One cannot establish scientifically sound analytical procedures by governmental edict.

SECOND, the Commission's smoking machine should not be used because its conceptual basis, i.e., separately analyzing the smoke from each puff, is not acceptable. It is very difficult to comment even on the hardware described in the Merfeld-Pillsbury paper because an adequate description of this complex machine has not been available. Specifically, there is no schematic diagram of the hydraulic system or of the syringe-manifold system with information as to approximate volumes. There is no timing diagram showing the time relationships in the complete (dual) system. A computer is shown in a diagram in the presentation, but is not described in the text. Some functional description should have been included.

Notwithstanding these deficiencies, it can still be confidently stated that the new machine proceeds upon the wrong basis by separately analyzing CO from each puff. This is

because there is a greater chance for error in determining the CO delivery of a cigarette on an individual per puff basis. The mere use of a puff-by-puff analysis increases manifold the error accompanying the final results on each variety of cigarettes tested. Under the approach proposed in the Merfeld-Pillsbury paper, per cigarette values will be the summation of individually measured and calculated puff values. The errors in final cigarette values will be greatly magnified using this approach. Following the Commission's proposal and assuming that a cigarette takes 10 puffs, each one of the 20 smoking positions will yield more than 50 pieces of CO data (10 values per cigarette, 5 cigarettes per port position, plus clearing puffs). Each of these values will have an error associated with it. These data must then be combined to obtain a final per port result comparable to the "tar" and nicotine measurements.

Moreover, the mere handling and manipulation of massive quantities of data inherently leads to error. In addition to the "tar" and nicotine analyses, the procedure proposed by Merfeld and Pillsbury, if applied to the analysis of 175 brands, would require approximately 175,000 more determinations. Added to this, the number of smokings involved will be increased by 25% when the monitor cigarettes are included, and the necessary clearing puffs must also be counted. This brings to well over 200,000 the number of pieces of data which must be processed for the CO analysis.

Thus, the present semi-annual determination of "tar" and nicotine which the Commission's laboratory now performs on a market sample of about 175 cigarette varieties will be weighted down with an extra burden of nearly a quarter-million additional measurements. This should emphasize the impracticality of making the analysis for carbon monoxide on a puff-by-puff basis.

Also, use of the per puff approach has one other inherent defect. Accurately determining CO content on low delivery cigarettes on a per puff basis is practically impossible. This is because of the extremely low concentrations of CO to be measured, especially in the initial puffs from a cigarette and in the clearing puffs. The error in each per puff determination may be as great as the CO value itself.

On a related matter, the undersigned have serious reservations about the reliability of the built-in calibration check. In the Merfeld-Pillsbury paper we found no indication of the calibration range to be used or the accuracy and precision obtained during measurements for carbon monoxide. This could be especially important at very high and very low concentrations of carbon monoxide. For example, the choice of a 0-10 scale range which would be suitable for the majority of cigarettes would seriously reduce the accuracy of measurements on highly ventilated low-"tar" cigarettes where very low CO concentrations may be encountered. Also, measurements of the low concentrations in fractional puffs and in clearing puffs will have reduced accuracy. On the other hand, the selection of a lower range

scale may be too low for carbon monoxide concentrations in many cigarettes, particularly in the later puffs.

The equipment used, such as small diameter tubing and miniature manifolds, is inherently unreliable. Specifically, the small diameter tubing which is incorporated to minimize dead volume may create pressure problems in transferring samples to the IR cell for analysis. This would translate to variability in analyzer response. Also, puff-by-puff analysis will require that a tremendous number of samples pass through the small tubing and the IR cell. This increases the chances of fouling and clogging. Frequent cleaning will be required along with careful attention to cell alignment to protect the accuracy of the end determination.

THIRD, even from the information presented it is clear that there are numerous design deficiencies in the machinery described.

For example, it has been reported in the literature that CO delivery of cigarettes increases with increasing puff number and increases during the puff. From these observations, it is unlikely that there is such a thing as a reliably representative portion of a puff applicable to all cigarette brands and types. The FTC machine allows one second for "the gas phase to thoroughly mix" prior to exhausting the gas to the IR analyzer. This is an extremely short time if one expects the smoke of all types of cigarettes to become thoroughly mixed prior to analysis. It is probable that complete mixing of the gas from a given puff may not occur within

the one second allowed for this purpose. This may be even more critical for fractional puffs. Obviously incomplete clearing of the system will permit mixing of the gas from two different cigarettes.

The new machine is mechanically complicated and may be more prone to breakdown or malfunction than the Phipps and Bird machine currently used by the FTC and the Tobacco Institute testing laboratories.

Specifically, the use of miniature components, such as solenoids, tubing and fittings to minimize dead volume, introduces inaccuracies and would pose a maintenance problem if this device were run on a daily basis.

Also, the Merfeld-Pillsbury machine uses plastic syringes rather than glass syringes which have worked over a long period of time. There is no basis for concluding that the plastic syringes will perform as well, and they may produce leaks.

Both a thermistor and a string cutoff means are mentioned but no preference was indicated in the paper. The undersigned have previously explained why the thermistor cutoff should not be used.

Since a gas flame from a hand-held lighter is proposed, it is probable that variable amounts of carbon monoxide from the flame will be drawn into the first puff. This could have a significant effect on the analysis of cigarettes yielding very low per puff concentrations of carbon monoxide. There is also the possibility of some variation in the amount of cigarette burned while being lit with a hand-held open flame.

FOURTH, the Commission should not use the new machine because it runs a serious risk of increasing the errors accompanying the Commission's "tar" and nicotine results. At the present time the Commission has spent twelve years trying to minimize errors in its "tar" and nicotine results which are obtained with one type of machine. Those results are widely disseminated by the Commission and included in advertising. Now the Commission proposes to switch to a new smoking machine, which is physically and mechanically different. For example, the new machine operates hydraulically as opposed to standard mechanical operation, and the new machine puffs all ports sequentially rather than simultaneously.

There is no assurance that resulting "tar" and nicotine data from the new machine will agree with that obtained from established equipment. It is well-known that subtle changes in smoking parameters can significantly affect smoke delivery.

Unless and until some comparative data are published showing "tar" and nicotine values obtained on the two machines, it would be unwise to switch to the new machine.

FIFTH, the Commission has taken precisely the wrong approach by arbitrarily selecting a single method for determining CO content and inviting comment as to that method.

It has been clearly established that the choice of the method will significantly affect the results which are obtained in CO determinations. For example, a CORESTA collaborative study

on smoke CO measurement by 16 laboratories in the United States and Europe reported values ranging between 15.8 to 20.5 mg/cig. from the same reference cigarettes. Five laboratories used various gas chromatographic methods while eleven laboratories used non-dispersive infrared devices similar to the proposed FTC equipment. The study concluded that reported CO variations were probably related to the lighting procedure, butt length accuracy and type of smoking machine.

Moreover, the state of the scientific art is developing rapidly. There are already several alternative methods for determining CO, all of which avoid the deficiencies in the method described by the Commission, and all of which may be more accurate than that described by the Commission.

For example, there has within the past year been developed methodology for simultaneous determination of "tar," nicotine and carbon monoxide which answers or avoids the potential problems in the Commission's approach. This is accomplished by adapting the standard Phipps and Bird 20-port smoking machine to perform the carbon monoxide analyses. The problems arising from the analysis of individual puffs are avoided by collecting the total gas phase from each port in storage bags, and sending this accumulated sample to the nondispersive IR analyzer at the conclusion of smoking on each pad. Both the smoking machine operation and the carbon monoxide

analysis including the data accumulation and calculation functions are handled by an inexpensive micro-computer. The accuracy of the method in present use is better than  $\pm 4\%$  of the determined carbon monoxide value, and the "tar" and nicotine analysis remains unchanged from that performed previously. The cost of the machine modifications required to make the conversion, including the IR analyzer, the micro-computer, all parts and labor is less than \$10,000. This approach is recommended in preference to embarking on a totally new and untried smoking machine and methodology.

B. Should CO Be Reported As Milligram Per Cigarette?

In answer to this second question, it is the view of the undersigned that the units used for reporting CO should be milligrams per cigarette. There are two further points which are critical in connection with reporting. The first is that any and all CO figures must contain a measure of the error associated with that figure, i.e.,  $A \pm E$  mg/cig. The second is that no determination can now be made as to whether results can properly be rounded to the nearest whole milligram. That determination can only be made when data from the new machine have been published and evaluated. To illustrate the point, if a result is  $5.1 \pm .8$  mg/cig. it would be improper to round that figure and report it as 5 mg/cig. If data from the new machine had been made available, the undersigned

could have commented on the scientific propriety of presenting values in terms of whole milligrams per cigarette.

C. Should The Gas Chromatographic Method Be Used For Nicotine?

As a general matter, the undersigned believe that changing the nicotine analysis method from the Griffith Still/Spectrophotometric method to the gas chromatographic method is desirable since the gas chromatographic method is more convenient, more accurate and has been thoroughly tested in a collaborative study by the AOAC. The data from this study are soon to be published in the Journal of the AOAC and are available to the Commission prior to publication if desired.

We cannot, however, at the present time specifically advise the Commission that it should make this change. The reason is that we have not seen any complete smoke analysis data obtained by the Commission Laboratory using the gas chromatographic method and there has been no collaborative study of this method by the Commission and Industry laboratories. If such data are made available (or if such a study is made), and they show that the Commission Laboratory is obtaining sufficient precision and reliability using this method, then we would advise the Commission to make this change for its next test.

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In conclusion, we would urge the Commission that there is no purpose to be gained by the determination or publication of cigarette carbon monoxide yields. The scientific literature does not support a conclusion that exposure to carbon monoxide from cigarette smoking has significant health consequences. Furthermore, no single method of carbon monoxide measurement in cigarette smoke has gained general acceptance in the scientific community either within or outside the cigarette industry. Therefore, any data presented, by any method, will be subject to question on grounds of accuracy and relevance. Both of these issues should be resolved in the scientific community before the Commission embarks upon this project.

Respectfully submitted,

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American Brands, Inc.

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Brown & Williamson Tobacco Corporation

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Liggett & Myers Tobacco Company, Inc.

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Lorillard

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Philip Morris, Inc.

Dated: February \_\_, 1979  
Washington, D.C.

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R. J. Reynolds Tobacco Company