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**Review of human smoking behaviour
and recommendations for a new ISO
standard for the machine smoking of
cigarettes**

*Évaluation des données relatives au comportement du fumeur et
recommandations relatives à une nouvelle norme ISO concernant le
fumage mécanique de cigarettes*



Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 17219 was prepared by Technical Committee ISO/TC 126, *Tobacco and tobacco products*.

0 Introduction

0.1 Editorial comments

This Technical Report is based on the report of the ad hoc Smoking Behaviour Review Team to ISO/TC 126. To meet ISO Central Secretariat requirements for Technical Reports the following editorial changes have been necessary.

- The Executive Summary has been made into a Conclusion.
- ‘Scope’ and ‘Abbreviated terms’ clauses have been added.
- The Bibliographies that appeared at the end of each chapter in the original report have been combined at the end of the Technical Report. Some footnotes have been replaced by notes in the text or by reference to the Bibliography.
- ISO Technical Reports are a work product of an ISO Technical Committee and as such do not have named authors.
- In the Introduction some repetition has been removed (two paragraphs describing the preparation of the report have been combined) and one paragraph was moved as a consequence.

0.2 Background

Smoking machines for measuring cigarette smoke yields were initially developed in the 1930s. The 35 ml puff volume currently used in both the International Organization for Standardization (ISO) and US Federal Trade Commission (FTC) methods was originally proposed by Bradford in 1936. Throughout the 1950s and early part of the 1960s various smoking machines were developed each using a set of parameters to define how the cigarette was smoked. Examination of the data showed that smoke yields were dependent on the smoking parameters used in the methodologies.

In 1966 the FTC in the US proposed a standardised machine smoking method with a smoking regime of 35 ml puff volume, 2 s puff duration and one puff per min. The rationale for adopting a standardised smoking regime was outlined in an FTC press release issued in 1967. The FTC stated that the method enabled products to be ranked in terms of their tar and nicotine yields. They also claimed that the yields obtained using their method would not provide individuals or groups of smokers with the precise amounts of tar or nicotine they would obtain from cigarettes. This limitation of the FTC method arises because smokers exhibit a wide range of smoking behaviour characteristics while the smoking machine uses a fixed standardised smoking regime.

Other national standards institutes had developed machine smoking methods in parallel to the activities in the US. Most of these adopted the 35 ml puff volume, 2 s duration and 1 puff per min regime, but there were differences between the various methods in factors such as butt lengths, type of smoking machine used, and the method of collecting smoke.

By the end of the 1980s a number of standardised machine smoking methods were in use worldwide. These included FTC, ISO and CORESTA methods, and methods used by the standards authorities in the UK, Germany, Canada, Australia, New Zealand and Japan. In 1988 ISO recommended that a standard worldwide smoking method was needed and they asked CORESTA to conduct the experimental work necessary to produce and validate a revised standard method. A comprehensive series of studies were subsequently conducted by CORESTA and a revised ISO method was introduced in 1991.

The ISO standard method is now used worldwide with the exception of the US and Japan. However, both the FTC method in the US and the Japanese standard method are very similar to the ISO method.

Periodically, the parameters used in the standardised machine smoking methods have been criticized for not being representative of the behaviour parameters produced by smokers. Critics have raised the following points.

- Many human smoking behaviour studies show that many smokers take larger and more frequent puffs than the standardised smoking machine.

- As a result of their more intensive puffing behaviour smokers may obtain higher smoke yields than those reported using standard methods.
- Some smokers have been observed to alter their smoking behaviour when switching to a lower yield cigarette e.g. increasing puff volume. This phenomenon is frequently referred to as “compensation”. All cigarettes are tested using the same parameters under the ISO/FTC method. Consequently, declared ISO/FTC yields would provide misleading information to smokers on the ranking of brands by smoke yields if they compensate to such an extent that rank order of yields is no longer maintained.
- The filter ventilation zones are unblocked when cigarettes are smoked using the ISO and FTC methods. However smokers may block some of the ventilation holes with their fingers or lips when smoking. Ventilation hole blocking may result in increases in smoke yields.

The WHO formed a group called the “WHO Study Group on Tobacco Product Regulation” (TobReg). During the first meeting of the TobReg group in October 2004 there was a discussion between TobReg members and representatives of ISO including the Secretariat of ISO/TC 126. TobReg expressed its view that *“the current ISO standard for machine measurement of cigarette emissions is not a valid means of comparing different brands of cigarettes relative to their emissions, human exposures that result from their use, or for purposes of regulation”*. TobReg requested that ISO modify the ISO machine standard for measuring cigarette emissions.

Representatives from the WHO Tobacco Free Initiative and TobReg were invited to present their views on the ISO method at the annual meeting of ISO/TC 126 in Geneva in 2004. It was decided that the following actions should be taken:

- 1) To consider an amendment to the scope of ISO 4387.
- 2) To review worldwide human smoking behaviour, uptake studies, and smoking methods in order to advise ISO/TC 126.
- 3) Based on the review outline in 2) to consider the development of a robust and practical smoking regime that as far as possible is representative of smokers’ behaviour and that has acceptable reproducibility and variability.
- 4) To report back to ISO/TC 126 with any proposals for a new work item.

0.3 Mandates

ISO/TC 126 proposed the formation and approved the membership of the present ad hoc group and prepared a detailed statement of work for that group. The purpose of the work was defined as:

- Identify one or more sets of values for smoking machine parameters for additional method(s).
- Propose machine smoking methods(s) more relevant to smoking behaviour which could reflect maximum yields.
- The existing ISO methods should be retained and evaluated as giving lower yields.

The ad hoc Smoking Behaviour Review Team was established with the following terms of reference.

- 1) To review worldwide human smoking behaviour documentation, uptake studies and smoking methods to advise ISO/TC 126.
- 2) To report maximum and minimum values for puff volume, puff duration, puff frequency, ventilation blocking, butt lengths and other parameters.
- 3) To recommend one or more sets of parameters for potential new practical machine smoking regimes in addition to the existing ISO standard (ISO 3308).
- 4) To identify gaps in existing knowledge.

0.4 Ad hoc Smoking Behaviour Review Team, ISO/TC 126

This report is the joint effort of the Smoking Behaviour Review Team members. The report begins with an Executive Summary outlining the recommendations of the ad hoc group. The Executive Summary was authored collectively by the ad hoc group. Each member of the ad hoc group prepared a chapter that addresses the issues named in the mandate.

The Executive Summary includes:

- a history and overview of machine smoking protocols;
- a review and summary of the published literature and some recent unpublished data on smoking topography, including a summary of puff volumes, puff durations, puff frequencies and puff numbers grouped according to ISO/FTC tar yields, geographical location and date of data collection;
- literature on filter ventilation and ventilation hole blocking;
- a review of the literature and a clause on butt length;
- an overview of studies that address the issue of cigarette smoking and nicotine intake and uptake.

0.5 Limitations

In the following clauses each of the main parameters of machine smoking are discussed. It is acknowledged that there are limitations to the use and the interpretation of smoking machine yields. Most important among the limitations of the machine smoking methods is the recognition that no machine standard can truly reflect the wide range of human smoking behaviour. People smoke cigarettes differently. The variability between smokers can be due to pharmacological as well as social, economic, and cultural differences. Furthermore smoking topography in the same person varies as a function of the time of day, social circumstance, time since the last cigarette, and the number of cigarettes smoked among other possible influences. Finally, puffing parameters differ over the course of a single cigarette. For example smokers may take larger and more frequent puffs at the beginning of a cigarette and smaller and less frequent puffs toward the end of the cigarette. It is also possible that blocking of filter ventilation holes differs over the course of smoking a single cigarette. Specifically, vent blocking may occur when some puffs are taken but not others. Thus the provisions of machine standards where all puffs are identical through the entire cigarette rod, the intervals between puffs are identical, the vent blocking is constant and the inter-puff interval is constant, does not reflect the large diversity in smoking behaviour.

In spite of these limitations the use of machine smoking represents a tenable solution to the complex problem of assigning and studying yields of commercially available cigarettes. The results of such tests are useful for the assessment of the delivery of components of tobacco smoke and for comparisons of cigarettes on the delivery of nicotine, tar, carbon monoxide and other components of tobacco smoke. The consideration of new parameters for the machine smoking regimen is appropriate because of changes in cigarettes and the consumption patterns of smokers.

Review of human smoking behaviour and recommendations for a new ISO standard for the machine smoking of cigarettes

1 Scope

This Technical Report was prepared by an ad hoc Smoking Behaviour Review Team to address the following terms of reference:

- a) to review worldwide human smoking behaviour documentation, uptake studies and smoking methods;
- b) to report maximum and minimum values for puff volume, puff duration, puff frequency, ventilation blocking, butt lengths and other parameters;
- c) to recommend one or more sets of parameters for potential new practical machine smoking regimes in addition to the existing ISO standard (ISO 3308);
- d) to identify gaps in existing knowledge.

2 Abbreviated terms

Avg	Average
CORESTA	Centre de Coopération pour les Recherches Scientifiques Relative au Tabac
DoH	Department of Health (formerly known as DHSS)
DHSS	Department of Health and Social Security
FTC	Federal Trade Commission
Ind.	Individual
RH	Relative Humidity
Run	The smoking run that the cigarette was smoked in
Tar	Nicotine Free Dry Particulate Matter (NFDPM)
Tipping	Overwrap - i.e. the wrapping material applied to the mouth end of the cigarette
TNCO	Tar, nicotine and carbon monoxide
TSNAs	Tobacco specific nitrosamines
UKAS	United Kingdom Accreditation Service
USPO	United States Patent Office
Yield	The concentration of analyte measured in the smoke (normally per cigarette) when smoked in a prescribed manner

cig ⁻¹	per cigarette
CV(%)	Coefficient of variation (relative standard deviation)

3 Smoking machine regimes

3.1 Abstract

The way that a human smokes a cigarette is extremely variable. Two smokers picked at random will probably not smoke the same brand of cigarettes in the same manner. A single individual will smoke two cigarettes of the same brand differently depending on a whole range of factors, e.g. on the time of day. Even during the time it takes to smoke one cigarette a single smoker may change his behaviour during the smoking process on that same cigarette, e.g. reducing puff volume towards the end of smoking the cigarette. Therefore it is not possible to develop a smoking regime which is capable of mimicking human smoking behaviour. The best that can be achieved is to design a smoking regime with a fixed set of parameters to achieve reproducible results that is loosely based on human smoking behaviour. The diversity of smoking behaviour allows plenty of scope for the development of a wide range of smoking regimes that can claim to be representative. An additional complication is that smoke yields of tar, nicotine and carbon monoxide have decreased for many brands over the last few decades and this has arguably had a significant effect on human smoking behaviour.

This Technical Report looks at current smoking regimes, why they are used, what are the important parameters that need to be controlled and how good are the regimes at determining reproducible smoke yields for tar, nicotine and carbon monoxide. In particular this Technical Report looks at:

- the purpose of a smoking regime;
- the development of the four major smoking regimes that are used today: ISO, FTC, Canadian Intense and Massachusetts;
- parameters that need to be controlled as part of a smoking regime;
- smoking machines — what are their limitations and how practicable would it be to develop a new smoking regime;
- the use of smoking regimes for products other than cigarettes and in the determination of analyte yields other than tar, nicotine and carbon monoxide.

3.2 General

This report looks at why (a) smoking regimes are used, (b) a history of how smoking machine regimes have developed since testing of cigarettes began, (c) current smoking machine regimes and (d) current smoking machine capabilities.

3.3 Why have a smoking regime?

Testing of cigarettes began many decades ago. "...some of the first workers to attempt to define a standard puff volume were Pyfl and Schmidt^[3] in 1933. From measurements made on seven different smokers, they recorded a mean puff volume of 40 cm³ (ml) of 2 s (second), taken twice a minute"^[4].

It would have soon become apparent that smoking machine parameters needed to be controlled if reproducible results for smoke yields were to be obtained. The current list of primary parameters that are controlled include:

- puff volume;
- puff duration;
- puff frequency;

- butt length (at which smoking should cease).

In addition other factors should be controlled to obtain reproducible results within and between laboratories when using the same analytical method. They include:

- conditioning of cigarettes;
- environmental conditions in which the smoking is performed;
- air flow across the cigarette;
- insertion depth of the cigarette into the holder;
- puff profile — this is a measure of puff flow rate — being a combination of puff volume and puff duration;
- type of trap;
- representative sample;
- vent blocking (yes/no).

3.4 What was the original reason for testing cigarettes and how were parameters selected?

One of the original reasons for testing cigarettes was to compare smoke yields from different cigarette brands. It was obvious from the beginning that:

- a) smokers can smoke different brands of cigarettes in different ways;
- b) a smoker smokes the same brand of cigarettes differently during the day. For example, one study found that "... smoking in situations that caused physical stress (e.g. when waiting) resulting in a shortening of puff interval (35 s instead of 43 s)"^[5];
- c) a smoker often changes the way the cigarette is smoked during the smoking process, the most common observation being that puff volume and duration decreases as the cigarette is smoked whereas puff interval increases. This might be due to satiation of the nicotine craving and an increase in "smoke concentration" as the cigarette is smoked by the consumer. However, Buzzi "concluded that the sensory consequences of the physicochemical changes in smoke composition between the first and last puff or other as yet unknown psychological factors are more likely candidates than nicotine satiation for explaining the typical changes in puffing behaviour along burning time of a cigarette."^[6]

Therefore, it was apparent that the parameters selected to operate a smoking machine would have to be a composite as it was not practicable to replicate human smoking behaviour.

3.4.1 Development of the ISO smoking regime

Joseph Johnson gives a good summary of how some of the early parameters for the ISO smoking regime were arrived at.

"In 1961, observations were made on 312 UK smokers by Research Services Ltd on behalf of the Tobacco Manufacturers Standing Committee. The average values from one cigarette type were found to 14 puffs, 12 min bare time, a frequency of 1,17 puffs per min and a butt length of 18 mm. When the same cigarette type was smoked on a machine it was found that a 25 cm³ (ml) puff volume of 2 s duration taken once per minute gave an alight time of 12 min and a butt length of 18 mm.^[7] These parameters were considered to be realistic and were adopted as the UK standard. During the same time period some other countries had standardised on the 35 cm³ puff although a 40 cm³ puff was used in the Federal Republic of Germany and Romania.^[8]

In 1969, on the initiative of the German Institute for Standardization (DIN), a Technical Committee on Tobacco and Tobacco Products was formed.^[9] One of the first actions of this group was to recommend the 35 cm³ puff volume of 2 s duration taken once a minute as standard — largely because most of the

participating laboratories had a substantial amount of data based on this regime”[4]. As a result of this recommendation the puff volume in the UK standard method was changed to 35 ml in 1970.

3.4.2 Development of the FTC smoking regime

The original methods for measuring tar and nicotine yields in cigarette smoke came from a variety of sources: “In 1936, the American Tobacco Company began using standard machine smoking conditions, which, to some extent, reflected the smoking habits of cigarette smokers at that time. The estimated sales-weighted average nicotine yields of the cigarettes smoked at that time were around 2,8 mg”[10]. By the early 1960s, different manufactures were using varying methodologies to obtain tar and nicotine smoke yields which meant that the results were not very comparable. Something needed to be done to sort the situation out.

The FTC prohibited manufacturers making claims about tar and nicotine yields that could not be substantiated by competent scientific proof. However as evidence grew about the potential harmful effects of smoking cigarettes, it was felt that consumers should be provided with information about tar and nicotine yields. This would enable them to choose a brand with e.g. a lower tar yield. Therefore, there was a requirement to establish a standardised testing protocol for assessing tar and nicotine smoke yields.

One of the earliest collaborative studies of a smoking method took place in 1964 and was based on work carried out by laboratories from the tobacco industry. Dr Ogg who worked for the US Department of Agriculture acted as the convenor. Cigarettes were conditioned for 24 h at 75 °F (23,9 °C) and 60 % Relative Humidity and 5 cigarettes were smoked per channel with a puff volume of 35 ml, a puff duration of 2 s and a puff frequency of 60 s.[11] TPM yields ranged from around 35 mg cig⁻¹ down to 20 mg cig⁻¹ and nicotine yields from 1,8 mg cig⁻¹ down to 1,1 mg cig⁻¹. In 1967, the FTC cigarette laboratory began operations based on Dr Ogg’s work and the methodology adopted was to take one puff of two seconds’ duration and 35 ml puff volume every minute. It was reported (Chapter 2 — Monograph 7 — FTC cigarette test method[12] that Harold Pillsbury had asked Dr Ogg how he had come up with the specific parameters of the collaborative trial protocol. He replied that they had been based on personal observations and since there was no such thing as an average smoker, he had selected parameters that seemed reasonable in light of his observations.

“In 1980 the protocol was broadened to include measurement of the carbon monoxide yields as well”[12].

3.4.3 Development of the Canadian Intense smoking regime

It was of concern to many that the ISO smoking regime produces yields on the low side of what a “typical” smoker could be reasonably expected to inhale. Work had been carried out by Labstat Inc. for the Federal Government of Canada to look at the effect of different smoking parameters on analyte yield. In one study: “Three levels of each of five smoking parameters: butt length, puff duration, puff interval, puff volume, and ventilation occlusion were examined, and the effects on puff number and total particulate matter (TPM) as well as gas phase, particulate phase, and total HCN yields were estimated”[13]. Based on these investigations, the legislators in the Canadian province of British Columbia proposed that a smoking regime be introduced with a 56 ml puff volume and a puff frequency of 26 s.[14] In addition ventilation holes on the filter would be fully blocked. It was felt that this regime would produce yields that would be more representative of maximum intake by the smoker. At a later date, the parameters were modified to 55 ml puff volume and 30 s puff frequency and adopted at the Federal level in Canada.

3.4.4 Development of the Massachusetts smoking regime

In 1996, the director of the Massachusetts tobacco control program proposed regulations which would require tobacco companies to report accurate nicotine ratings for cigarettes. Additional testing of cigarettes was to be performed when determining nicotine yields using different puff volumes and frequency and requiring some form of vent blocking. This was part of a strategy to provide meaningful cigarette labelling.

The original intention was to choose two sets of smoking machine parameters that better represent (a) what an “average smoker” might inhale and (b) maximal yields that a “heavy smoker” might produce.

The “average smoker” regime may have been based on a proposed specification change to the FTC protocol. The proposed regulations were revised before coming into force in 1997 and the “heavy smoking regime” was dropped.

3.4.5 Deciding on a suitable butt length

Many surveys of butt lengths have taken place and the measurement of butt lengths can be done precisely so that an accurate mean can be produced. However, smokers are less obliging in their smoking and a wide range of values have been found. In one study, a mean butt length of 22,1 mm was found for filter cigarettes (1959) in West Germany but 10 years later another study found the length to be 30,6 mm for the same country. The authors found that “There are significant differences in butt length for different sections of the population, e.g. sex, place, occupation, geographic location, and economic conditions, brand, etc.”^[15]. Not surprisingly early smoking regimes often used different butt lengths. Harmonization of standards has reduced the number of alternatives and improved precision of smoke yields obtained by a smoking machine. However, it might be argued that this is at the expense of flexibility to reflect what happens with smoking behaviour in different parts of the world.

3.4.6 “Early smoking machines”

It has been reported that some of the very early smoking machines used a column of water to generate the puff and that termination was done manually by removal of the burning cigarette when the glowing coal reached a certain point on the cigarette. A patent for a smoking machine was registered with the USPO as far back as 1941 and was based on a suction pump which pulled smoke from the cigarette and then, by means of a mechanical valve and gears, directed the cigarette smoke into a gas analyser chamber on the exhaust stroke of the pump. The puff duration was 2 s and the frequency was once every 30 s. Alas the puff volume does not seem to be given in the patent. Another patented device was designed to compare different types of cigarettes, e.g. plain and filtered brands.^[15] By 1969, a recognizable rotary machine had been patented and had been designed so that all the first puffs from a set of cigarettes would be collected on one filter, all the secondary puffs on another filter, and so on.^[16]

3.4.7 Selecting appropriate parameters

The selection of suitable values for smoking machine parameters was largely a pragmatic exercise based on a few smallish surveys of smokers and taking into account smoking machine capabilities which at that time were fairly limited. Advances in technology, developing knowledge of the analytical method, method validation and collaborative studies led to the introduction of standards to allow for conditioning of cigarettes, setting up the smoking machine to produce a bell shaped puff profile (some of the original machines worked on constant flow rather than constant volume), etc. The desire to measure smoke yields consistently and the additional requirement to determine carbon monoxide yields meant that air flows needed to be controlled and to this day there is a slightly different approach between ISO and the FTC as to the best way of achieving this.

For ISO smoking conditions, an airflow meter is placed in the position where a cigarette would burn within the smoking fume hood. The standard requires an air velocity value of $200 \text{ mm s}^{-1} \pm 50 \text{ mm s}^{-1}$ per individual channel and a mean of $200 \text{ mm s}^{-1} \pm 30 \text{ mm s}^{-1}$. FTC smoking airflow is set at the minimum required to remove side-stream smoke without appreciably increasing static burn rate. This can be checked with a reference cigarette, e.g. Kentucky Reference 2R4F, which would be smoked to determine the proper airflow rate had been set by comparison to historical control data.

3.4.8 The requirement for reproducible results

The early selection of methods and smoking regimes had been done on an individual country basis. ISO asked CORESTA to carry out method validation studies and collaborative trials to improve and standardize the method. Following on from this work a set of ISO standards were issued in 1991, e.g. Determination of total particulate matter using a ... smoking machine.^[17] The adoption by the European Economic Community of a 15 mg “tar” ceiling on all cigarette brands sold in 1993 in Europe meant that (a) laboratories from different countries would need to use the same validated method to determine the tar and nicotine yields in cigarette smoke and (b) the method had to be reproducible — it

would not be acceptable for a cigarette brand tested in the UK to pass yet the same brand/production batch tested in Germany to fail.^[18]

The work by CORESTA demonstrated the need for laboratories to have good Quality Assurance procedures, for example accreditation under ISO/IEC 17025^[1] by a national “authoritative body” (e.g. UKAS). Laboratories also needed to show their methods are reproducible by e.g. taking part in a proficiency testing scheme. The latest set of results from the South East Asia Collaborative Study (Round 12, 2004, 49 participants) showed that most laboratories can achieve good smoke nicotine yields (in terms of repeatability and reproducibility) when smoking the CORESTA CM4 monitor cigarette using ISO standards. The yearly CORESTA collaborative trials shows that there has been an improvement with time of the variability between laboratories as good practice has been disseminated between participants (e.g. the harmonization of air flows for different types of smoking machines).

3.4.9 How was the data to be used?

When the ISO smoking regime was first introduced, cigarettes were markedly different from those manufactured today in terms of smoke yield. In the 1972 UK survey of about 110 cigarette brands,^[19] only 5 brands had a tar yield of less than 10 mg/cig. (the current maximum permitted yield in the European Union) and 10 brands exceed 30 mg/cig. — the highest being 38 mg/cig. Plain cigarettes were much more prevalent, filters were relatively simple devices and filter ventilation was in its infancy — the median tar value was 20 mg/cig. The purpose of testing cigarette brands was to allow ranking of brands and provide consumers with information to make a choice. Information provided from the UK study included the following:

“The brands are listed in the order of “tar” yieldDifferences between brands of up to 2 mg of “tar” can generally be ignored.....There are good grounds for believing that those smokers who choose to continue smoking are rather less likely to damage their health if they smoke cigarettes with a low “tar” yield.”^[19]

It was realized with time that the parameters chosen were not “... reflecting average human behaviour and leading to published yields universally under estimating yields actually obtained by the average smoker”.^[19]

The response from the UK Department of Health (DHSS) was “... that values presented in tables ... have never been intended to be actual yields obtained by any one smoker. Rather, they enable brands to be ranked.”^[20]

Similar points had been previously made in the 1967 FTC press release in the US stating the purpose of the FTC method:

The test method was not designed “to determine the amount of “tar” and nicotine inhaled by any human smoker, but rather to determine the amount of tar and nicotine generated when a cigarette is smoked by a machine in accordance with prescribed method.”¹⁹ The objective was to provide smokers with information that would allow them to switch to a lower tar brand.

3.4.10 The problem of using the data in a meaningful manner

In 1994 the FTC method was reviewed by an ad hoc expert committee which made several recommendations and comments about the difficulty of using smoking machine data effectively in informing the public of the relative risk of smoking different brands.

“The question involved in the purpose, methodology, and utility of the FTC protocol are complex medical and scientific issues that require ongoing involvement of Federal health agencies, including”

“A reduction in *machine-measured* tar yield from 15 mg tar to 1 mg tar does not reduce relative risk from 15 to 1”.

“Information from the testing system is useless to smokers unless they have ready access to it.”

“The available data suggests that smokers misunderstand the FTC test data”.

It should be remembered that smoking yields vary with the design of the cigarette and under the conditions in which the cigarette is smoked. This variation is complex and so cannot be accurately predicted from a single smoking regime.

3.5 What are smoking regimes currently used for?

The smoking regimes are used for several different purposes:

- a) Manufacturers use the smoking regime to determine e.g. tar, nicotine and carbon yields in cigarette smoke when the product is smoked to the prescribed conditions. This information is used to make a declaration about the product. In the European Union, there is a requirement to print the tar, nicotine and carbon monoxide smoke yields on the side of the packet. In some countries there is an agreement to declare other analyte yields in cigarette smoke; e.g. in Canada there is now a requirement to declare benzene, formaldehyde and hydrogen cyanide yields.
- b) Regulators use the smoking regime to verify the packet declaration. In addition, counterfeit cigarettes are a significant problem in some countries. Regulators use the smoking regime to test the suspect goods with a view to putting the counterfeiter on trial for making a false declaration.
- c) Public health bodies use data obtained from testing cigarettes to disseminate information about the risks of smoking cigarettes. In many countries, legislators have established a regulatory limit above which cigarette smoke yields must not exceed when smoked under prescribed conditions.
- d) Manufacturers use the smoking regime to compare brands in terms of smoke yields. This information is put on the side of the packet and until recently often with a descriptor (e.g. "lights") to tell the consumer something about the product. Which smoking regime (if any) is most appropriate for ranking brands and how the information can be presented in a meaningful way to consumers is a contentious issue between manufacturers' and health authorities at the present time.
- e) Manufacturers use the smoking regime to evaluate the effect of product design. For example, if a new type of filter is introduced, then a manufacturer will test the product to see what effect it has on TNCO yields. Using a range of smoking regimes allows the manufacturer to explore the effects of changes in cigarette design on smoke yields under different conditions. If the smoking regimes chosen reflect e.g. common and maximum smoking parameters then the test results produced will lead to a better understanding of how human smoking behaviour influences smoke yields.
- f) Manufacturers use the smoking regime as part of their Quality Control, to ensure that changes in tobacco blend or the manufacturing process does not have a significant effect on the product.
- g) Manufacturers and others^[22] have used smoking regimes to determine a range of analyte yields in cigarette smoke. The results can be used in many ways, e.g. (a) comparison of analyte yields (e.g. carbon monoxide and benzene) from one brand of cigarette; (b) ranking of brands by analyte yield and (c) comparison of analyte yields when using different smoking regimes.

Table 1 — Smoking regimes in use today

Regime	ISO ^a	FTC	Massachusetts	Canadian Intense
No. of cigarettes smoked per pad	Max TPM 30 mg cig ⁻¹			
Linear (44 mm Ø) Rotary (92 mm Ø)	5 20	5 20	3 10	3 10
Puff volume	35 ml ± 0,3 ml	35 ml ± 0,5 ml	45 ml ± 0,5 ml	55 ml ± 0,5 ml
Puff duration	2 s ± 0,05 s	2 s ± 0,05 s	2 s ± 0,05 s	2 s ± 0,05 s
Puff frequency	60 s ± 0,5 s	60 s ± 0,5 s	30 s ± 0,5 s	30 s ± 0,5 s
Ventilation holes	Open	Open	50 % blocked	100 % blocked
Conditioning atmosphere	60 % RH ± 3 % RH 22 °C ± 1 °C min 2, max 10 d	60 % RH ± 2 % RH 23,9 °C ± 1,1 °C ^b min 1, max 14 d	60 % RH ± 2 % RH 23,9 °C ± 1,1 °C min 1, max 14 d	60 % RH ± 3 % RH 22 °C ± 1 °C min 2, max 10 d
Smoking environment	60 % RH ± 5 % RH 22 °C ± 2 °C	60 % RH ± 3 % RH 23,9 °C ± 2 °C	60 % RH ± 3 % RH 23,9 °C ± 2 °C	60 % RH ± 5 % RH 22 °C ± 2 °C
Air flow Linear ind. Port Linear avg. & Rotary ^c	200 ± 50 ml min ⁻¹ 200 ± 30 ml min ⁻¹	Sufficient to exhaust smoke – about 120 ml min ⁻¹	Sufficient to exhaust smoke – about 120 ml min ⁻¹	200 ± 50 ml min ⁻¹ 200 ± 30 ml min ⁻¹
Butt length (whichever is the highest value)	Tipping + 3 mm or filter + 8 mm or 23 mm from butt	Tipping + 3 mm or 23 mm from butt	Tipping + 3 mm or 23 mm from butt	Tipping + 3 mm or filter + 8 mm or 23 mm from butt
<p>a A very similar smoking regime to ISO is used in Japan, the only significant difference being that the minimum butt length is 30 mm or tipping plus 3 mm. It has been reported [16] that Japan is likely to change to the ISO Regime in 2002 but the author has been unable to confirm this change. The CORESTA smoking regime is identical to the ISO smoking regime.</p> <p>b 23,9 °C is equivalent to 75 °F.</p> <p>c FTC and Massachusetts smoking regimes only make reference to linear smoking machines.</p>				

3.6 Smoking machine capabilities

Tar, nicotine and carbon monoxide yields are normally determined by machine smoking. Machines have improved dramatically since the first machine was patented in 1941. Basically two types of smoking machines are used: linear and rotary machines. Depending on the aim and the analytes to be determined by the smoking test, each type presents advantages and disadvantages.

There are two major manufacturers of smoking machines in the world: Borgwaldt KC GmbH and Cerulean plc. Both manufacturers have designed at least two types of machine, one targeted at TNCO smoking where a high throughput is required and one machine which allows for greater flexibility and can be used for a wide range of applications.

Smoking machines produced by both manufacturers are capable of smoking to the three main regimes.

3.6.1 Puff volume

Earlier models of smoking machines used a 50 ml glass syringe designed to deliver a 35 ml puff volume. This could be adjusted to deliver a 45 ml puff volume but a 55 ml puff volume required either the use of a larger syringe or combining two channels together so that the volume drawn by two adjacent syringes are combined. Older models normally have to be modified to deliver a larger puff volume, e.g. moving the bar on the linear smoking machine.

On newer versions of smoking machines, the puff volumes can be varied quite easily by means of software and smoking machines are capable of producing a puff volume greater than 55 ml. However, the mechanics of the system means that it becomes increasingly more difficult to deliver larger volumes in a short period of time with good precision. Therefore, for example, a 100 ml puff volume with a 1 s puff duration is not practicable with the current design of smoking machines.

3.6.2 Puff interval

The design of the rotary smoking machine means that it is only practicable to select a puff interval of 60 s when smoking 20 cigarettes. If the rotary smoking machine is used in 10 cigarette mode with a puff duration of 2 s, then the minimum puff frequency cannot be less than 30 s, i.e. a 2 s puff duration with a 1 s puff interval.

3.6.3 Puff duration

Puff duration is the parameter most difficult to reduce. It takes a certain amount of time to operate the syringe/piston drive in a smooth motion, open and close valves and produce a bell shaped profile. The piston then has to return to its original position ready to take the next puff. Therefore, a large puff volume combined with a short puff duration might require some fundamental design changes by the smoking machine manufacturer.

3.6.4 Butt length termination

Originally butt length determination was performed by the glowing end of the cigarette burning through a cotton thread which released a micro switch to terminate the smoking of the cigarette. There is a small time lag between the glowing coal reaching the butt length and the smoking of the cigarette being terminated. More sophisticated equipment tends to be used today, normally based on an infrared sensor which detects when the hot coal has reached a certain point along the length of the cigarette.

3.6.5 Air flows and puff profile

Air flows are much better controlled than when smoking machines were originally designed and enclosing the smoking machines in a box/hood means that adjustment of air flow over the cigarette is relatively easy to set up and adjust. Advances in software and the control systems mean that it is an easy matter to set up a puff profile, bell shaped being the most common type.

3.6.6 Ventilation hole blocking

There is a concern by workers in the field that whereas full blocking of ventilation holes to smoke to the Canadian Intense smoking regime is easy to perform in a reproducible manner, sealing 50 % of the ventilation holes to achieve the conditions required for the Massachusetts smoking regime can be much trickier and is currently impracticable if large volumes of cigarettes have to be tested.

NOTE It is relatively easy to achieve 100 % ventilation blocking by taping the cigarettes but it is difficult to achieve e.g. 50 % vent blocking consistently, in particular for different size diameters of cigarette brands.

A new type of holder could be designed by the smoking machine manufacturers to achieve partial ventilation blocking. NB There would need to be a sufficient market for the holders to cover production costs (i.e. a new ISO standard will be produced making partial ventilation blocking a requirement). The smoking method using the new style of holder would need to undergo validation, probably by means of a collaborative trial, to ensure that acceptable reproducibility between laboratories is achieved. The whole process from design of the new holder and its manufacture through to final validation would take at least a year to set up.

3.6.7 Trapping system

Total particulate matter in mainstream cigarette smoke is invariably trapped using a Cambridge glass fibre filter pad and the vapour phase component (containing the carbon monoxide) trapped in "gas-collection" bags for later analysis. Larger puff volumes and more puffs per min would mean a large increase in NFDPM yield with a significant chance of overloading the pad so that breakthrough would occur for the higher "tar" yielding cigarettes (e.g. > 30 mg cig⁻¹). This can be addressed in two ways — use a larger pad if the design of the smoking machine allows enough room to fit larger holders or reduce the number of cigarettes smoked per determination. The latter may well lead to poorer precision in analyte yields as there is less chance that "random variations" in the sample and the smoking process

will be averaged out. The large volume of cigarette smoke generated by longer cigarettes may exceed the capacity of the bag but a simple solution is to fit larger bags to the smoking machine.

3.6.8 Other types of smoking

Following the introduction of ISO 15592-3[2] for smoking of fine-cut smoking articles, both smoking machine manufacturers have introduced a holder that complies with the standard. Except for conditioning and butt length and the holder, other parameters remain the same as in ISO 3308.

The demand for smoking to determine analytes yields other than TNCO has grown significantly over the last couple of decades. Smoking machine manufacturers have therefore developed machines which allow for different types of trap to catch the analyte under investigation, e.g. impingers can be used to trap volatile components in cigarette smoke.

There is not yet a standard for smoking other materials containing tobacco though eventually there may be a requirement for smoking Moassel products using a standardised Hookah pipe and FCSA containing a prescribed mixture of tobacco and cannabis resin to allow for a semiquantitative comparison of smoke yields with cigarette smoking. It is not envisaged that it would be practicable to set up a smoking regime for pipe tobacco or bidis.

Similarly the demand for side-stream measurements has meant that both manufacturers are looking to design an effective way of measuring side-stream on a regular basis using a routine analytical smoking machine if the demand is there.

3.7 A look into the future

The additional flexibility that new smoking machines allow, means that some investigatory work is now being performed by researchers to see what effect a range of smoking “conditions” have on tar, nicotine and carbon monoxide yields. This may be linked to observed human smoking behaviour that has been observed and “quantified” or to intake studies, e.g. measuring the amount of nicotine that is being trapped by the cigarette filter when smoked by a consumer.

3.8 Smoking regimes (historical)

Previous smoking regimes	Parameters
Tobacco Research Council	Puff volume 35 ml Puff duration 2 s Puff frequency one a minute Butt length 20 mm for untipped cigarettes; 20 mm for tipped cigarettes or length of paper + 2 mm; 23 mm or overwrap + 2 mm for tipped cigarettes over 80 mm in length, (air flows set and measured in tri duct, different style holder, cigarettes conditioned but smoking environment not conditioned)
Federal Trade Commission	23 mm; length of filter and overwrap + 3 mm if the total exceeds 23 mm
CORESTA	23 mm for untipped cigarettes, 23 mm or the length of the filter plug plus 8 mm or length of overwrap plus 3 mm - whichever is the longer.

Health Canada	<p>Puff volume 56 ml</p> <p>Puff duration 2 s</p> <p>Puff frequency 28 s</p> <p>Butt length 20 mm for untipped cigarettes; 20 mm for tipped cigarettes or length of paper + 2 mm; 23 mm or overwrap + 2 mm for tipped cigarettes over 80 mm in length</p> <p>Ventilation holes blocked</p> <p>(air flows set and measured in tri duct, different style holder, cigarettes conditioned but smoking environment not conditioned)</p>
Massachusetts	<p>(proposed 'heavy smoker' regime)</p> <p>Puff volume 60 ml</p> <p>Puff duration 2 s</p> <p>Puff frequency 26 s</p> <p>Ventilation holes blocked</p> <p>(proposed 'average smoker' regime)</p> <p>Puff volume 45 ml</p> <p>Puff duration 2 s</p> <p>Puff frequency 34 s</p> <p>Ventilation holes 50 % blocked</p>

4 Summary of literature data on smoking topography

4.1 Abstract

One aspect of smoking behaviour has been termed smoking topography, i.e. the way smokers puff on a cigarette. Literature on smoking topography (1956 – 2004) was reviewed, focusing on parameters such as puff volume (individual and total), puff duration, puff interval, and number of puffs from a given cigarette, and how they may vary with cigarette “tar” yield, as determined by ISO/FTC machine smoking. Forty-six reports were identified as containing viable data, from which 100 data sets were extracted.

Significant differences in human puffing behaviour and ISO/FTC machine smoking parameters were found. When data were grouped according to machine-smoked ISO/FTC cigarette “tar” yield ranges (≥ 14 mg, 8 mg to < 14 mg, 3 mg to < 8 mg, and < 3 mg), puffing intensities increased as “tar” yield decreased.

Mean puff volume is larger than the 35 ml used in ISO/FTC testing. The overall mean was calculated as 48,3 ml. The mean puff volume increased from 48,1 ml, 47,8 ml, 54,7 ml, 57,2 ml, for cigarette ISO/FTC “tar” yields of ≥ 14 mg, 8 mg to < 14 mg, 3 mg to < 8 mg, and < 3 mg, respectively. The reported total puff volume increased from higher “tar” to lower “tar” yield cigarettes. The overall mean was calculated as 658 ml. The mean total puff volume increased from 567 ml, 611 ml, 817 ml, 890 ml, for cigarette ISO/FTC “tar” yields of ≥ 14 mg, 8 mg to < 14 mg, 3 mg to < 8 mg, and < 3 mg, respectively. The mean puff interval for all “tar” groups was less than the 60 s used in ISO testing; the overall mean was calculated as 26 s (range: 11 s to 53 s; 10th %ile 18 s, 90th %ile 38 s).

In addition to the large diversity in smoking behaviour, there is a complex relationship between puffing parameters, smoke constituent yield, smoke intake (i.e. mouth level exposure), and smoke constituents uptake. This Technical Report contributes to bridge the gap between potential smoke intake and existing machine smoking methods.

4.2 Introduction and methods

A survey of 160 publications from the scientific literature (1956 – 2004) was conducted for the purpose of extracting information on the way cigarettes are smoked by adult smokers. These publications

were initially identified using subject-search software and Philip Morris International literature files. Parameters such as puff volume (individual and total), puff duration, puff interval and number of puffs from a given cigarette, and how they may vary with cigarette “tar” yield as determined by ISO/FTC machine smoking, were of primary interest, and were entered in an Excel® spreadsheet¹⁾. Any other parameters that were reported were recorded. A variety of devices for measurement of the puff parameters were used in these studies. Detailed discussion of methods and procedures used in each study is beyond the scope of this summary.

The first step was to develop criteria to determine whether a report dealing with the topic of smoking topography contained useful information. Some publications were identified by the search software based on limited mention of smoking behaviour, but included no data. Only reports that contained numerical data were used, and in no case were graphical presentations of data interpolated into numeric values. Data were not taken from studies in which the subjects were part of a short-term “switching” study or were required to smoke cigarettes of different “tar” yields from their usual brands. Studies were not included in which smokers had been deprived of smoking for more than a few hours before data were collected, or in which subjects were asked to take any drugs or other substances unless baseline data were available. Most of the reports were derived from laboratory settings where “topography devices” had been used, and therefore, the influence of blocking ventilation holes cannot be assessed. There is evidence suggesting that smoking in laboratory settings yields about 30 % higher smoke deliveries than smoking under “natural” conditions. Puff concatenation was not considered.

Using these criteria, 45 reports were identified as containing viable data. However, only one publication was available reporting topography data of subjects smoking cigarettes with < 3 mg “tar” delivery. The ad hoc group decided to accept unpublished data sets adding topography data from 250 smokers to this particular “tar” category (see references^[32] and^[33] Dixon 2004 a, b), increasing the total number of reports to 47. Some reports contain multiple sets of data, and the total number of data sets extracted was 100. The total number of subjects n in the data sets were $n = 2\ 432$.

Not all of the publications reported results for all of the parameters of interest. ISO or FTC “tar” ranges for the cigarettes used were available in only some of the publications, and sometimes cigarette descriptors included “low nicotine,” “medium nicotine,” “low tar,” “medium tar” or similar. Data summarized here were taken from the publications shown in [3.5](#).

NOTE Forty-seven reports are listed in [3.5](#), but only 46 were used (Guyatt 1989a and 1989b) containing data from the same study.

Publications that were considered but not used are shown in the bibliography. Table 9 provides a condensed version of the spreadsheet that was used.

4.3 Results

Table 2 shows a summary of the puff volume and puff number data including a breakdown by “tar” range. The data reported in the literature are generally mean values with varied types of associated statistics. In the tables below, a mean value is the mean of the means reported in the literature and standard deviation is that in those means. Puff number is the number of puffs taken by the smoker on a single cigarette. The “tar” values are a mixture of ISO and FTC machine-smoked values. Puff volume is the volume of individual puffs in millilitres (ml), whereas total puff volume is the total volume puffed from a cigarette (ml). These data provide an overview of the puff volume and puff number for cigarettes of different machine-smoked “tar” yield ranges. These groupings are somewhat arbitrary and other group definitions could be considered. Some adjustment was made to the “tar” range values to attempt to balance the number of studies in each category.

1) Available upon request via the Secretariat of ISO/TC 126

Table 2 — Summary of puff volume and puff number data

“Tar” yield	Number of reports	Mean number of puffs	Mean puff volume (ml)	10 th %ile puff volume (ml)	90 th %ile puff volume (ml)	Mean total puff volume (ml)
All data	46	13,2	48,3	35,6	63,5	658
≥ 14 mg	14	12,5	48,1	37,7	63,5	567
8 – < 14 mg	10	12,3	47,8	41,0	55,7	611
3-8 mg	10	14,6	54,7	43,8	66,3	817
< 3 mg	3	15,3	57,2	48,4	63,3	890

NOTE Some of the reports did not specify the “tar” yield of the cigarettes used. The mean total puff volume (reported) is the mean of the values reported in individual publications.

Table 3 shows the topography data that were available from 14 reports for cigarettes in the FTC/ISO “tar” range of ≥ 14 mg.

Table 3 — Topography data for cigarettes ≥ 14 mg “tar”

	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (ml)	Mean number of puffs × mean puff volume (ml)
Mean	12,5	48,1	26,1	1,9	567	597
SD	1,3	10,7	8,8	0,4	152	160
Median	12,1	46,5	25,6	1,9	524	528
Max	14,7	66,0	40,7	2,6	872	950
Min	10,8	26,0	13,3	1,3	345	401
10 th %ile	10,9	37,7	17,3	1,4	407	462
90 th %ile	14,2	63,5	39,2	2,3	735	782

NOTE The mean total puff volume (reported) is the mean of the values reported in individual publications. The mean number of puffs × mean puff volume is the mean of the product of the number of puffs times the puff volume for those publications that reported both. Because some publications reported one of the parameters but not the other, the values in the two columns are not identical.

Table 4 shows the topography data that were available from 10 reports for cigarettes in the FTC/ISO “tar” range of 8 mg to < 14 mg.

Table 4 — Topography data for cigarettes 8 mg to < 14 mg “tar”

	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (ml)	Mean number of puffs × mean puff volume (ml)
Mean	12,3	47,8	27,3	1,8	611	595
SD	2,2	6,3	8,7	0,3	154	164
Median	12,6	46,6	24,7	1,8	598	590
Max	16,1	56,7	53,0	2,3	890	913
Min	7,0	37,1	20,8	1,2	344	329
90 th %ile	14,9	55,7	39,0	2,1	833	815
10 th %ile	9,4	41,0	21,0	1,5	473	402

Table 5 shows the topography data that were available from 10 reports for cigarettes in the FTC/ISO “tar” range of 3 mg to < 8 mg.

Table 5 — Topography data for cigarettes 3 mg to < 8 mg “tar”

	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (ml)	Mean number of puffs × mean puff volume (ml)
Mean	14,6	54,7	22,6	2,0	817	818
SD	3,0	9,7	7,1	0,3	247	275
Median	13,6	54,3	21,6	2,0	705	723
Max	18,6	70,3	35,2	2,6	1292	1308
Min	9,9	36,0	11,0	1,6	563	460
90th %ile	18,4	66,3	32,6	2,3	1183	1215
10th %ile	10,8	43,8	15,8	1,7	600	540

Table 6 shows the topography data that were available from 3 reports for cigarettes in the FTC/ISO “tar” range of < 3 mg.

Table 6 — Topography data for cigarettes < 3 mg “tar”

	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (ml)	Mean number of puffs × mean puff volume (ml)
Mean	15,3	57,2	18,9	1,9	890	889
SD	2,7	8,9	0,7	0,1	189	267
Median	15,1	60,4	18,7	1,9	873	909
Max	18,8	63,4	19,7	2,0	1135	1192
Min	12,3	44,5	18,3	1,7	678	547
90th %ile	17,7	63,3	19,5	2,0	1065	1121
10th %ile	13,1	48,4	18,4	1,8	728	642

Table 7 shows a breakdown of the basic topography data with respect to the decade of publication.

Table 7 — Summary of topography by decade of publication

	Number of data sets	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean total puff volume (ml)
All data	100	13,2 ± 2,6	48,3 ± 0,8	25,7 ± 8,1	657 ± 197
1970 - 1980	4	10,9 ± 1,1	38,5	36,8 ± 8,7	n/a
1981 - 1990	38	13,7 ± 2,7	44,9 ± 12,4	25,7 ± 7,9	568 ± 158
1991 - 2000	38	12,5 ± 2,5	50,0 ± 9,7	26,8 ± 8,6	673 ± 208
2001 - 2005	16	14,6 ± 2,0	53,0 ± 7,9	21,4 ± 1,9	784 ± 166

NOTE No numeric data were found prior to 1978. Only one puff volume was reported in the period 1970 - 1980, so no standard deviation could be calculated. Mean total puff volume is the mean of the product of puff volume and number of puffs for each study. This value is used rather than the mean of the reported total puff volumes to make use of additional data when total puff volume was not reported. n/a: data not available.

Table 8 shows a breakdown of the basic topography data with respect to the geographic locations of the subjects.

Table 8 — Summary of smoking topography by geographic location of the subjects

	Number of data sets	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean total puff volume (ml)
All data	100	13,2 + 2,6	48,3 ± 10,8	25,7 ± 8,1	657 ± 197
Americas	42	12,0 ± 1,9	50,9 ± 10,5	28,7 ± 9,3	624 ± 152
Europe	58	14,0 ± 2,7	46,8 ± 10,9	24,7 ± 7,2	683 ± 221
NOTE Americas includes studies from the United States, Canada and Brazil. Europe includes EU countries and Switzerland.					

4.4 Discussion and conclusions

Because of inconsistencies in the way that “tar” values are reported in the literature (ranges, approximate values, etc.), and especially because of the limited data available for the low “tar” cigarettes, it is difficult to perform statistical analyses on the relationships between “tar” and the smoking topography parameters. Correlation between FTC/ISO “tar,” and the number of puffs, puff volume and total puff volume with case-wise deletion of missing data resulted in correlation coefficients (*r*) between “tar” and these parameters of $-0,36$ ($P = 0,009$, $N = 50$), $-0,38$ ($P = 0,006$, $N = 51$) and $-0,55$ ($P = 0,001$, $N = 46$), respectively. All of the correlations are statistically significant ($P < 0,05$). The implication is that smoking intensity tends to increase as “tar” decreases.

The results of this literature survey may be summarized as follows:

- Mean puff volume is larger than the 35 ml used in ISO testing and may show increasing volumes from high to low “tar” cigarettes. The overall mean was calculated as 48,3 ml. The mean puff volume increased from 48,1 ml, 47,8 ml, 54,7 ml, 57,2 ml, for cigarette “tar” yields of $\geq 14, 8$ mg to < 14 mg, 3 mg to < 8 mg, and < 3 mg, respectively.
- The mean reported total puff volume increased from higher “tar” to lower “tar” yield cigarettes. The overall mean was calculated as 658 ml. The mean total puff volume increased from 567 ml, 611 ml, 817 ml, 890 ml, for cigarette “tar” yields of $\geq 14, 8$ mg to < 14 mg, 3 mg to < 8 mg, and < 3 mg, respectively.
- The mean number of puffs may slightly increase from higher “tar” to lower “tar” yield cigarettes. The overall mean number of puffs was calculated 13,2.
- The mean puff interval for all “tar” groups was less than the 60 s used in ISO testing; the overall mean was calculated as 26 s (range: 11 s – 53 s; 10th %ile 18 s, 90th %ile 38 s).
- Lastly, there is considerable variation between smokers in the way cigarettes are smoked.

Using the information summarized here, estimates of cigarette smoke constituent yield more closely reflecting smoker behaviour than obtained from ISO machine-smoked results may be feasible. It should be pointed out that the puffing parameters are not independent and that a change in one parameter could directly influence other parameters.

Table 9 — Condensed spreadsheet of topography data — All data

All data																			
Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography Measurements 1 = Plowshare 2 = Pickens 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	% Vent.	Mean no. of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)	
EU	1978	Guillerm	0	4	8		30,9	1,66						12,0	38,5	40,7	1,85		462
EU	1978	Ashton			8			1,00	1		0,969					24	1,47		
EU	1978	Rawbone		4	5				1		0,53		9,8		43,6	1,74			
EU	1978			4	7				1		0,78		10,9		38,8	1,92			
EU	1982	Battig	1	5	67	22	11,8	0,86					12,1	43,7	24,8	2,28	528	529	
EU	1982		2	5	43	21	11,0	0,79					13,0	37,1	24,7	1,99	481	482	
EU	1982	Russell	0		12	38	12,0	1,10	1,50				14,7	39,8	25,6	2,30	547	585	
US	1983	Gritz	1	4	8	28			1,10				9,5	65,6	47,2	2,20	600	623	
US	1983	Herring			11				1,03		1,42		13,1	43,3	35,0	1,65		565	
US	1983	Gust		4	8								9,0	43,7	48,4	1,60	380	393	
EU	1983	Adams	0	4	10									44,2	25,9	1,88	614		
EU	1984	McBride	0	6	9						1,53		15,7	42,1	25,3	2,14		661	
EU	1984		0	6	9				1		1,23		14,6	47,5	21,9	2,16		694	
EU	1984		0	6	9				1		1,94		15,3	38,2	23,1	1,89		584	
EU	1984	Hopkins	0		6		15,0		1		1,44			53,8		1,71	455		
EU	1984	Nil	2	6	10								14,8	41,1	25,9	1,67	619	608	
EU	1984		2	6	10								14,7	39,5	25,7	1,57	579	581	
EU	1985	Medici	0		17								13,7	43,1	18,7	2,20		590	
EU	1985		0		10								15,3	36,9	20,5	1,90		565	
EU	1985		1		7								19,3	35,7	16,1	1,60		689	
EU	1985		0		15								14,0	30,7	18,2	2,10		430	

Table 9 (continued)

All data																				
Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography measurements 1 = Plowshare 2 = Pickens 3 = Stratham 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig)	Nicotine delivery (mg/cig)	% Vent.	Mean no. of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)		
EU	1985		0		32									15,3	35,3	23,1	1,80	540	540	
EU	1985		1		10									14,7	34,6	18,3	2,10	509	509	
EU	1986	Nil	1	6	69	25	11,8	0,88					12,6	42,3	22,9	2,18	512	533	533	
			2	6	48	24	9,8	0,71					12,5	41,4	21,7	2,02	510	518	518	
E	1986	Nil, Woodson	0											12,7	30,3	28	2,20	376	385	385
US	1986	Hughes	0	2	19	24		0,90	3		0,9		11,9			1,58				
US	1986		0	2	27	21		-0,90	3		0,9		10,4			1,56				
EU	1986	Woodman	0	7	9	22	16,0	1,30	1,50				14,0	47,2	19,6	1,90	417	661	661	
US	1987	Hatsukami	0	2	12	29														
US	1987		0	2										13,4			1,16			
US	1987		0	2										11,1			1,38			
US	1987	Hatsukami	0											12,1			1,20			
EU	1987	Woodman	0	7	10		9,0	0,90	1,50				12,1	43,6	24,1	1,90	520	528	528	
EU	1987	Puustinen	0		8		4,0	5,0					18,4	36	11,0	2,20	649	662	662	
EU	1987		0		8		14,0	15,0					13,6	26	13,3	1,80	345	354	354	
US	1988	Hatsukami	0	2	10	35		0,60	1,15				15,3			1,30				
EU	1989	Nil	0	5	15			10,10	0,78				22,6	27,4	30,2		605	619	619	
EU	1989	Guyatt	0	5	28	25							13,9	47,2	34,2	2,10	603	656	656	
US	1990	Bridges	1		5			0,28	0,43				13,2	85,4	23,9	2,48	1142	1127	1127	

Table 9 (continued)

All data																		
Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography Measurements 1 = Plowshare 2 = Pickets 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	% Vent.	Mean no. of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)
US	1990				16			0,50 0,70					11,4	63,7	26,5	2,31	686	726
US	1990				22			0,71 0,90					11,1	54,1	26,8	1,94	578	601
US	1990				65			1,05 1,10					10,6	52,2	25,8	1,93	529	553
US	1990				17			1,11 1,20					11,4	62,4	26,7	2,05	693	711
US	1990				14			1,40 1,60					10,2	64,7	33,0	2,22	601	660
EU	1991	Kolonen	0	4	18	9	5,0	0,40					16,8	64,0	16,3	2,60	1045	1075
EU	1991				10	9	15,0	0,90					14,0	62,3	18,4	2,60	740	872
EU	1991	Hofer	0	6	18		2,47	0,10 0,30				63,0	12,3	44,5	18,3	1,97	678	547
EU	1991		0	6	18		5,00	0,40 0,60				54,6	11,8	45,2	19,0	1,95	596	533
EU	1991		0	6	18		9,53	0,70 0,90				32,3	11,4	40,0	21,7	2,03	467	456
EU	1991		0	6	18		14,97	1,00 1,20				8,4	10,9	36,8	17,0	2,19	405	401
EU	1992	Rieben	0	4	28								10,5	29,3				308
US	1992	Robinson	1	4	5		7,5	0,60					13,6	52,0	23,1	2,21	678	707
US	1992						7,4	0,06					12,8	51,0	21,4	2,33	634	653
EU	1992	Kolonen	0	4	18		6,3	0,40					18,4	66,9			1198	1231
EU	1992		0		18		6,3	0,40					18,6	70,3			1292	1308
EU	1992		0		10		14,2	0,90					14,4	66,0			872	950
EU	1992		0		10		14,2	0,90					12,1	64,6			716	782
EU	1995	Hee	1	3	11	14	0,9 3,9	0,09 0,40					9,9	61,0	35,2	2,04	563	604
EU	1995		2	3	25	13	0,9 3,9	0,09 0,40					13,6	54,3	25,6	1,88	732	738
EU	1995		1	3	10	12	4,9 10,8	0,49 0,86					12,7	53,4	26,5	2,06	653	678
EU	1995		2	3	26	10	4,9 10,8	0,49 0,86					13,0	46,0	27,3	1,70	598	598

Table 9 (continued)

Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography measurements 1 = Plowshare 2 = Plickens 3 = Stratham 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range		ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig)	Nicotine delivery (mg/cig)	% Vent.	Mean no. of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)
							ISO/FTC Tar range	ISO/FTC Nicotine range											
EU	1995		1	3	22	13	12,7	18,4	0,97	1,19				12,1	55,1	28,3	2,24	635	667
EU	1995		2	3	14	15	12,7	18,4	0,97	1,19				12,6	53,4	27,7	2,07	667	673
EU	1995	Reeves			40			5,9	0,52					10,6	43,4	32,3	1,55		460
EU	1995				21			8,6	0,91					9,5	42,7	40,7	1,71		406
EU	1995				19			13,8	1,32					9,2	42,9	38,2	1,56		395
US	1995	Djordjevic	0	4	8	14	8,0	11,0	0,70	0,80				12,0	52,0	28,3	1,70	606	624
US	1995		0	4	4	18	13,0	17,0	1,00	1,20				11,0	46,0	33,0	1,30	470	506
US	1995	Bentrovato	0	4I	13						18	1,5		10,8	46,9	40,7	1,98		507
US	1996	Brauer	0	2	7	30								10,3	29,1	28,2	1,90		300
US	1996	Ahijevych	2	4	16									13,8	48,4	20,7	1,80	660	668
US	1996		2	4	17									15,8	43,5	19,8	1,50	666	687
US	1996		2	4	15									13,6	42,7	22,6	1,70	579	581
US	1996		2	4	18									15,8	48,5	18,2	1,66	734	766
US	1997	Djordjevic	1	4	1		8,0	11,0	0,70	0,80				7,0	47,0	53,0	1,20	344	329
US	1997		1		1		8,0	11,0	0,70	0,80				11,0	56,0	32,0	1,50	613	616
US	1997		2		1		13,0	17,0	1,00	1,20				11,0	46,0	32,0	1,40	524	506
US	1997	Ahijevych	2		18													660	
US	1997		2		19													666	
US	1999	Eissenberg	1	1	38	23									54,8		1,53		

All data

Table 9 (continued)

All data																			
Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography measurements 1 = Plowshare 2 = Pickens 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	% Vent.	Mean no. of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)	
US			2	1	30	22								41,6			1,19		
US	2000	Djordjevic	0		56	15	7,7	9,5	0,60	0,80			12,7	48,6	21,3	1,50	615	617	
US	2000				77	16	15,0	15,8	1,09	1,13			12,1	44,1	18,5	1,50	523	534	
US	2003	Lee	0	1	7								r	30,8	19,9	0,90			
US	2003		0	1	10									45,1	23,2	1,20			
EU	2003	Dixon			13		9,5		0,77	1	1,11	51	16,0	55,4	20,9	1,75	877	886	
EU	2003				13		8,8		0,48	1	0,69	51	16,1	56,7	20,8	1,80	890	913	
EU	2003				13		8,7		0,81	1	1,17	52	14,4	53,6	21,4	1,69	755	772	
EU	2003				13		8,1		0,10	1	0,09	48	14,1	55,6	21,1	1,77	766	784	
EU	2003				13		7,7		0,22	1	0,34	51	15,6	55,8	20,0	1,84	839	870	
US	2004	Hughes	0	1	34	31							11,6	49,0			547	568	
US	2004		0	1	34	30							12,7	50,0			612	635	
US	2004	Strasser	0	1	113	21			0,20	1,70			12,7	54,8	24,8	1,6	676	696	
EU	2004	Dixon	0	8	100		1,2	0,12					18,8	63,4	18,7	1,91	1135	1192	
EU	2004		0	8	100		2,8	0,28					15,0	57,6	19,7	1,88	844	864	
EU	2004		0	8	100		4,8	0,48					16,6	58,6	21,7	1,85	939	973	
EU	2004		0	8	100		10,0	1,00					12,6	46,2	24,7	1,91	558	582	
US	2004	Dixon	0				1,0	0,10					15,1	63,2		1,74	901	954	
US	2004		0	8			5,6	0,54					12,5	52,8		1,74	644	660	

Table 9 (continued)

All data																			
Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography Measurements 1 = Plowshare 2 = Plickens 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig)	Nicotine delivery (mg/cig)	% Vent.	Mean no. of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)	
	N reports	46	N subjects	2432									No. puffs	Puff volume (ml)	Puff interval (s)	Puff duration (s)	Total volume (measured) (ml)	Calc. total volume (ml)	
														13,2	48,3	25,9	1,8	658	647
													sd	2,6	10,9	8,1	0,3	194	203
													median	47,0	24,1	1,9	615	617	
													max	85,4	53,0	2,6	1292	1308	
													min	26,0	11,0	0,9	344	300	
													90th	63,5	38,3	2,2	892	910	
													10th	35,6	18,3	1,4	465	408	

Table 10 — Condensed spreadsheet of topography data — Topography data for cigarettes ≥ 14 mg “tar”

Region	Year	First Author	Gender 0 = Both 1 = Male 2 = Female	Method of Topography Measurements 1 = Plowshare 2 = Pickets 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range		ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)
							ISO/FTC Tar range	ISO/FTC Nicotine range										
EU	1978	Guillerm	0	4	8		30,9	1,66					12	38,5	40,7	1,85		462
EU	1982	Russell	0		12	38	12,0	19,0	1,10	1,50			14,7	39,8	25,6	2,3	547	585
EU	1984	Hopkins	0		6			15,0		1,50		1,44		53,75		1,71	455	
EU	1986	Woodman	0	7	9	22	16,0	18,0	1,30	1,50			14	47,2	19,6	1,9	417	
EU	1987	Woodman	0	7	10		9,0	18,0	0,90	1,50			12,1	43,6	24,1	1,9	520	528
EU	1987	Puustinen																
EU	1987	Kolonen	0		8		14,0	15,0		0,97			13,6	26	13,3	1,8	345	
EU	1991				10	9		15,0		0,90			14	62,3	18,4	2,6	740	
EU	1991	Hofer	0	6	18			14,97	1,00	1,20			10,9	36,8	17	2,19	405	401
EU	1992	Kolonen	0		10			14,2		0,90			14,4	66			872	950
EU	1992		0		10			14,2		0,90			12,1	64,6			716	782
EU	1995	Hee	1	3	22	13	12,7	18,4	0,97	1,19			12,1	55,1	28,3	2,24	635	667
EU	1995		2	3	14	15	12,7	18,4	0,97	1,19			12,6	53,4	27,7	2,07	667	673
US	1995	Djordjevic	0	4	4	18	13,0	17,0	1,00	1,20			11	46	33	1,3		506
US	1995	Bentrovato	0	4	13			15,0		1,20			10,8	46,9	40,7	1,98		507
US	1997	Djordjevic	2		1		13,0	17,0	1,00	1,20			11	46	32	1,4	524	506
US	2000	Djordjevic			77	16	15,0	15,8	1,09	1,13			12,1	44,1	18,5	1,5	523	

Table 10 (continued)

≥ 14 mg "tar"																	
Region	Year	First Author	Gender 0 = Both 1 = Male 2 = Female	Method of Topography Measurements 1 = Plowshare 2 = Pickens 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)
	N reports	14		N subjects	232							Number of puffs	Puff volume (ml)	Puff interval (s)	Puff duration (s)	Total volume (measured) (ml)	Calc. total volume (ml)
												Mean	48,1	26,1	1,9	567	597
											SD	1,3	10,7	8,8	0,4	152	160
											Mean	12,1	46,5	25,6	1,9	524	528
											Max	14,7	66,0	40,7	2,6	872	950
											Min	10,8	26,0	13,3	1,3	345	401
											90th	14,2	63,5	39,2	2,3	735	782
											10th	10,9	37,7	17,3	1,4	407	462

Table 11 — Condensed spreadsheet of topography data — Topography data for cigarettes 8 mg to < 14 mg “tar”

8 mg to < 14 mg “tar”																	
Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography Measurements 1 = Plowshare 2 = Pickens 3 = Stratham 4 = PM5TC 5 = Other 6 = Creighton 7 = CGC Ltd 8 = Filtrona 9 = SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)
EU	1982	Battig	1	5	67	22	11,8	0,86 ± 0,33				12,1	43,7	24,8	2,28	528	529
EU	1982		2	5	43	21	11,0	0,79 ± 0,29				13	37,1	24,7	1,99	481	482
EU	1986	Nil	1	6	69	25	11,8	0,88				12,6	42,3	22,9	2,18	512	533
			2	6	48	24	9,8	0,71				12,5	41,4	21,7	2,02	510	518
EU	1991	Hofer	0	6	18		9,53	0,70				11,4	40	21,7	2,03	467	456
EU	1995	Hee	1	3	10	12	4,9	108	0,49	0,86		12,7	53,4	26,5	2,06	653	678
EU	1995		2	3	26	10	4,9	108	0,49	0,86		13	46,0	27,3	1,7	598	598
EU	1995	Reeves			21		8,6			0,91		9,5	42,7	40,7	1,71		406
EU	1995				19		13,8			1,32		9,2	42,9	38,2	1,56		395
US	1995	Djordjevic	0	4	8	14	8,0	11,0	0,70	0,80		12	52,0	28,3	1,7		624
US	1997	Djordjevic	1	4	1		8,0	11,0	0,70	0,80		7	47,0	53	1,2	344	329
US	1997		1		1		8,0	11,0	0,70	0,80		11	56,0	32	1,5	613	616
US	2000	Djordjevic	0	4	56	15	7,7	9,5	0,60	0,80		12,7	48,6	21,3	1,5	615	617
EU	2003	Dixon			13		9,5			0,77	1,11	16	55,4	20,9	1,75	877	886
EU	2003				13		8,8			0,48	0,69	16,1	56,7	20,8	1,8	890	913
EU	2003				13		8,7			0,81	1,17	14,4	53,6	21,4	1,69	755	772
EU	2003				13		8,1			0,10	0,09	14,1	55,6	21,1	1,77	766	784
EU	2004	Dixon	0	8	100		10,0	1,00				12,6	46,2	24,7	1,91	558	582

Table 11 (continued)

8 mg to < 14 mg "tar"																		
Region	Year	First author	Gender 0 = Both 1 = Male 2 = Female	Method of topography measurements 1 = Plowshare 2 = Pickens 3 = Stratham 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)	
	N reports	10	N subjects	539								Number of puffs	Puff volume (ml)	Puff interval (s)	Puff duration (s)	Total volume (measured) (ml)	Calc. total volume (ml)	
												Mean	47,8	27,3	1,8	611	595	
												SD	6,3	8,7	0,3	154	164	
												Mean	46,6	24,7	1,8	598	590	
												Max	56,7	53,0	2,3	890	913	
												Min	37,1	20,8	1,2	344	329	
												90th	55,7	39,0	2,1	833	815	
												10th	41,0	21,0	1,5	473	402	

Table 12 — Condensed spreadsheet of topography data — Topography data for cigarettes 3 mg to < 8 mg “tar”

Region	Year	First Author	Gender 0 = Both 1 = Male 2 = Female	Method of topography Measurements 1 = Plowshare 2 = Pickens 3 = Stratham 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range		ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar Delivery (mg/cig.)	Nicotine Delivery (mg/cig.)	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)	
							4,0	5,0											
EU	1987	Puustinen	0	4	8		4,0	5,0	0,32				18,4	36	11	2,2	649		
EU	1991	Kolonen	0	4	18	9	5,0	5,0	0,40				16,8	64	16,3	2,6	1045	1075	
EU	1991	Hofer	0	6	18		5,00	0,40	0,60				11,8	45,2	19	1,95	596	533	
US	1992	Robinson	1	4	5		7,5		0,60				13,6	52	23,1	2,21	678	707	
US	1992						7,4		0,06				12,8	51	21,4	2,33	634	653	
EU	1992	Kolonen	0	4	18		6,3		0,40				18,4	66,9			1198	1231	
EU	1992		0		18		6,3		0,40				18,6	70,3			1292	1308	
EU	1995	Hee	1	3	11	14	0,9	3,9	0,09	0,40			9,9	61	35,2	2,04	563	604	
EU	1995		2	3	25	13	0,9	3,9	0,09	0,40			13,6	54,3	25,6	1,88	732	738	
EU	1995	Reeves			40			5,9	0,52				10,6	43,4	32,3	1,55		460	
EU	2003	Dixon			13		7,7		0,22	1	0,34		15,6	55,8	20	1,84	839	870	
EU	2004	Dixon	0	8	100		4,8	0,48					16,6	58,6	21,7	1,85	939	973	
US	2004	Dixon	0	8	50		5,6	0,54					12,5	52,8		1,74	644	660	
	N reports	10	N subjects	324															
													Mean	54,7	22,6	2,0	817	818	
												SD Mean	3,0	9,7	7,1	0,3	247	275	
												Median	13,6	54,3	21,6	2,0	705	723	

Table 12 (continued)

3 mg to <8 mg "tar"																			
Region	Year	First Author	Gender 0 = Both 1 = Male 2 = Female	Method of topography Measurements 1 = Plowshare 2 = Pickens 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nico-tine delivery method 1 = Butt 2 = NE 3 = Other	Tar Delivery (mg/cig)	Nico-tine Delivery (mg/cig)		Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)	
													Max	18,6	70,3	35,2	2,6	1292	1308
													Min	9,9	36,0	11,0		1,6	563
													90th	18,4	66,3	32,6	2,3	1183	1215
													10th	10,8	43,8	15,8	1,7	600	540

Table 13 — Condensed spreadsheet of topography data — Topography data for cigarettes < 3 mg “tar”

Region	Year	First Author	Gender 0 = Both 1 = Male 2 = Female	Method of Topography Measurements 1 = Plowshare 2 = Pickets 3 = Stratham PM5TC 4 = Other 5 = Creighton 6 = CGC Ltd 7 = Filtrona SAP4	N	Cig/Day	ISO/FTC Tar range	ISO/FTC Nicotine range	Nicotine delivery method 1 = Butt 2 = NE 3 = Other	Tar delivery (mg/cig.)	Nicotine delivery (mg/cig.)	Mean number of puffs	Mean puff volume (ml)	Mean puff interval (s)	Mean puff duration (s)	Mean total puff volume (measured) (ml)	Calc. mean No. of puffs x mean puff volume (ml)	
																		Number of puffs
EU	1991	Hofer	0	6	18		2,47	0,10 0,30					12,3	44,5	18,3	1,97	678	547
EU	2004	Dixon	0	8				0,12					18,8	63,4	18,7	1,91	1135	1192
EU	2004		0	8	100		2,8	0,28					15,0	57,6	19,7	1,88	844	864
US	2004	Dixon	0		50			0,10					15,1	63,2		1,74	901	954
	N reports	3	N subjects	268											< 3 mg tar			
									Mean				15,3	57,2	18,9	1,9	890	889
									SD Mean				2,7	8,9	0,7	0,1	189	267
									Median				15,1	60,4	18,7	1,9	873	909
									Max				18,8	63,4	19,7	2,0	1135	1192
									Min				12,3	44,5	18,3	1,7	678	547
									90th				17,7	63,3	19,5	2,0	1065	1121
									10th				13,1	48,4	18,4	1,8	728	642

5 A brief review of the incidence, degree and consequences of filter ventilation hole blocking

5.1 Abstract

This clause is a brief overview of studies aimed at addressing the issue of filter ventilation blocking by smokers. The objective of the review was to provide data that may be used for determining the role of ventilation blocking in a revised ISO machine smoking regime.

The literature concerning the incidence of vent blocking in smokers indicates that vent blocking is more likely to occur with lip rather than finger contact with the vent holes. A wide range of vent blocking incidences is reported in the literature. Differences in the methodologies used for detecting vent blocking may account for the wide spread in incidence data.

Most studies indicate that the effect of vent blocking on smoke yields is greater when cigarettes are smoked by smoking machines than when they are smoked by humans. This is because smokers tend to reduce their puffing intensity when ventilation zones are partially or fully blocked whereas the smoking machine takes a constant puff irrespective of the degree of vent blocking.

A number of studies have indicated that during deliberate, maximal vent blocking with lips or fingers smokers can block only around 50 % of the ventilation zone.

Partial or complete vent blocking has a minimal effect on the smoke yields of moderately ventilated cigarettes (<60 % ventilation) during human smoking. However vent blocking can produce significant yield increases in highly ventilated cigarettes when smoked by humans.

5.2 Filter ventilation — Basic information

Filter ventilated cigarettes have been marketed for over 30 years and were developed to reduce the yields of all smoke components, especially gas phase components. Filter ventilation is an essential cigarette design tool for the production of cigarettes with low tar yields (e.g. < 10 mg) and is necessary for the reduction of gas phase components such as CO. However, filter ventilation is not the sole method used for reducing smoke yields. Other yield reduction features, such as high efficiency filters, porous cigarette papers, reduced tobacco weights, use of expanded tobacco and reconstituted tobacco sheet are incorporated into today's very low yield cigarettes.

Filter ventilation can be achieved by laser perforation, electrostatic perforation or by mechanical perforation. The perforation can occur online during the manufacture of cigarettes (e.g. on line laser perforation) or tipping paper can be purchased pre-perforated and be applied to filters incorporating porous plug wraps during cigarette manufacture.

The filter ventilation zones are typically placed 11 mm to 16 mm from the mouth of the filter with the location being to a large extent dependant on the length of the filter. Ventilation can comprise of 1 row of ventilation holes placed around the circumference of the filter, or it can be a zone including several rows of ventilation holes.

5.2.1 The effect of ventilation hole blocking on smoke yields during machine smoking

A number of researchers have investigated the effects of partially or fully occluding filter ventilation holes on the tar, nicotine and CO yields obtained during machine smoking of cigarettes. The data from a number of these studies are discussed below:

- Kozłowski et al. (1980)^[193] measured the effects of partial (50 %) and complete blocking of filter ventilation holes on the machine smoked tar, nicotine and CO yields of a 4 mg tar yield cigarette. They used the standard FTC/ISO machine smoking regime i.e. 35 ml puff volume, 2 s puff duration and 1 puff per min. Under the partial block condition, tar yields increased by 60 %, nicotine by 62 % and CO by 73 %. Fully blocking the ventilation holes increased tar by 186 %, nicotine by 118 % and CO by 293 %.

- Kozlowski et al. (1982)^[194] examined the effects of vent blocking on a range of 1 mg tar yield products from US, UK and Canada. The yields obtained under the standard FTC regime were compared with those obtained from fully blocked cigarettes smoked under a more intense smoking regime (47 ml puff volume, 2,4 s duration and a 44 s inter-puff interval). The increases in tar yield ranged from 1 360 % to 3 800 %, the range for nicotine was 720 % to 1 767 %, and for CO 870 % to 4 180 %.
- Rickert et al. (1983)^[204] investigated the effects of ventilation hole blocking on 28 brands of Canadian cigarettes. In this study the vent block effect was determined by comparing the yields obtained under a “moderate” smoking regime (48 ml puff volume, 2,4 s duration, 44 s inter-puff interval) with those obtained under the same regime but with 50 % of the ventilation holes covered with tape. Ventilation blocking produced increased yields for the “Lowest tar” cigarettes (1 mg to 2 mg tar yield) of 160 % for tar, 130 % for nicotine and 150 % for CO. The corresponding figures for the “Ultra-light” cigarettes (3 mg to 5 mg) were 63 % for tar, 57 % for nicotine and 75 % for CO. Partial vent blocking of the Light cigarettes (6 mg to 14 mg tar yield) increased tar by 38 %, nicotine by 36 % and CO by 36 %.
- Reeves et al. (1997)^[203] examined the effects of partial (50 %) or complete ventilation hole blocking on the machine smoked yields (FTC regime) of a range of US “Low Ultra” (1 mg to 3 mg tar yield - average vent level 75 %), “High Ultra” (4 mg to 6 mg tar — average vent level 56 %) and “Lights” (7 mg to 12 mg tar — average vent level 30 %) cigarettes. Partial vent blocking increased the yields of the “Low Ultra” cigarettes by 111 % for tar and 106 % for nicotine. Complete ventilation blocking resulted in an increase of 372 % tar and 269 % for nicotine in the Low Ultra cigarettes. Partial block increases of 54 % for tar and 35 % for nicotine, and complete block increases of 109 % and 70 % respectively were seen for the “High Ultra” cigarettes. The yields of the “Lights” cigarettes were increased under the partial vent block condition by 6 % for tar and 1 % for nicotine, these increased to 19 % for tar and 9 % for nicotine under the complete block condition.
- Baker Dixon and Hill (1998)^[188] measured the influence of partial (50 %) and complete ventilation hole blocking on the tar, nicotine and CO yields (ISO machine smoking conditions) of two UK cigarettes, a 4 mg (55 % ventilation) and a 9 mg tar yield (28 % ventilation) product. Partially blocking the vent zones of the 4 mg product increased tar yield by 27 %, nicotine by 26 % and CO by 58 %. Complete ventilation hole blocking produced increases of 83 % for tar, 51 % for nicotine and 175 % for CO. A partial block of the higher yield 9 mg product produced an increase of 9 % for tar and nicotine and 16 % for CO. The corresponding figures for the complete ventilation block were 16 % for tar, 11 % for nicotine and 46 % for CO.

One can draw a number of general conclusions from these machine smoking studies.

- 1) Partial and complete ventilation hole blocking can produce marked increases in smoke yields when cigarettes are machine smoked.
- 2) The relative increases in smoke yields produced by ventilation hole blocking are greater for the more highly ventilated “lowest tar” yield cigarettes than for the less ventilated “Light” cigarettes.
- 3) The effects of vent blocking are generally more pronounced for CO yields than for either tar or nicotine yields.
- 4) The degree of vent blocking is not linearly related to the corresponding increases in smoke yields. For example most studies show that the yield increases are much greater when going from the 50 % to 100 % vent block condition than from the unblocked to 50 % vent block condition.

5.2.2 Incidence of ventilation hole blocking in smokers

A number of experimental approaches have been used in attempts to determine the incidence of filter ventilation hole blocking in smokers. These include:

- Questionnaires asking smokers whether they think they block some or all of the vent holes with their lips or fingers.

- Direct observation or video recordings of smokers to determine whether they have finger contact with the cigarette filter while puffing on the cigarette.
- Visual observation of the tar staining patterns of the mouth end of ventilated cigarette filters.
- Measurements of the depth of insertion of the cigarettes into the mouths of smokers to determine whether the vent holes may be occluded by the smokers' lips.

5.2.3 Questionnaire approaches

Kozlowski et al. (1980)^[193] interviewed a group of smokers and they originally thought that 32 % to 69 % of smokers of low tar cigarettes blocked the vent holes with fingers, lips or adhesive tape. In 1983 Ferris (reported in Baker and Lewis (2001)^[187] conducted a study in which smokers were interviewed and video-recorded in three UK cities. The smokers were asked if they blocked the ventilation holes of the cigarette during normal smoking. 52 % of the 97 smokers interviewed claimed that they blocked the ventilation holes during smoking. 71 % of these smokers believed that the vent blocking would occur as a consequence of their normal holding of the cigarette during smoking.

5.2.4 Observation and video recording

Ferris 1983 (reported in Baker and Lewis (2001)^[187] video-recorded 136 smokers of ventilated cigarettes while they were participating in a series of interviews. These included the 97 smokers who were asked questions about ventilation hole blocking behaviour. The smokers were allowed to smoke during the interview sessions and video recordings of 133 smoking events were obtained. Three of the smokers did not smoke during the interviews. Of these 133 smokers, 118 (89 %) smokers had no finger contact with cigarette while they were puffing on the cigarette. Only 5 smokers (4 %) had finger contact with the cigarette during all puffs. Consequently, finger blocking of the vent zones was a possibility in a small minority of the smokers in the Ferris (1983) study. Interestingly, many of the smokers who had **no** finger contact with the cigarette during puffing gave answers to the questionnaire indicating that they thought they would block ventilation holes as a consequence of the way in which they held their cigarette during smoking.

Hill 1983 (reported in Baker and Lewis (2001)^[187] used a video recording technique to determine the position of the fingers on the filter when finger contact occurs during the puff. Hill indicated that the range of finger placement, when it occurred, was 15 mm to 24 mm from the mouth end of the filter with a mean value of 18,3 mm. This implied that when fingers were in contact with the filter they generally upstream of the ventilation zone as most cigarettes have vent zones placed 11 mm to 16 mm from the mouth end of the filter.

5.2.5 Filter stain patterns

Kozlowski et al. (1980)^[193] originally believed that the **degree** of filter ventilation hole blocking could be gauged by examining the tar staining patterns on the mouth end of spent filters. They claimed that a "bulls-eye" pattern, i.e. where the tar staining was in small circle in the centre of the mouth end of the filter, indicated no vent blocking. A heavy stain across the entire mouth end of the filter was according to Kozlowski et al. (1980)^[8] indicative of complete vent blocking. Stain patterns between these two extremes were claimed to be indicative of partial vent blocking.

There have been a number of reported studies assessing vent blocking by use of the filter staining method and these have been reviewed in detail by Baker and Lewis (2001).^[187] Briefly, the studies produced the following figures on the incidence of vent blocking:

- Kozlowski et al. (1982)^[194] reported that of 39 filters taken from 39 smokers, 15 % indicated complete vent hole blocking, and 44 % partial vent hole blocking.
- Zacny and Stitzer (1988)^[209] examined 1 631 filters from only 10 smokers. Of these 0,1 % indicated complete blockage and 28 % indicated partial vent blocking.
- Kozlowski et al. (1988)^[195] examined 135 filters from an unreported number of smokers. Of these 19 % were rated as being fully blocked and 39 % partially blocked.

- Kozlowski et al. (1989)^[196] examined 14 filters from 14 smokers and reported 21 % fully blocked and 29 % partially blocked.
- Kozlowski et al. (1994)^[198] assessed 158 filters from an unreported number of smokers. Of these 27 % were rated as being fully and 26 % partially blocked.
- Djordjevic et al. (2000)^[189] assessed an unreported number of filters from 56 smokers of US low nicotine yield cigarettes and 77 smokers of US medium nicotine yield cigarettes. They did not attempt to differentiate between full and partial block but recorded evidence of some degree of vent blocking in 21 % of the low and 30 % of the medium yield cigarettes.

The ability to differentiate between the different degrees of ventilation hole blocking by using stain patterns has been questioned in a number of studies. Lombardo et al. (1983)^[200] assessed the accuracy of rating the degree of blockage by using the stain technique and concluded that the method may prove too unreliable to be useful. Kozlowski and coworkers conducted studies subsequent to those listed above (Pillitteri, Morse and Kozlowski (1994),^[201] Kozlowski et al. (1996)^[197] and now conclude that the stain technique cannot reliably discriminate between a 50 % and a 100 % vent block but may be a useful method to detect the presence or absence of vent blocking.

Helms (1983)^[190] and (1984)^[191] demonstrated that the filter stain pattern on unblocked filters can be influenced by a number of cigarette design features. These include the degree of ventilation, number and size of vent holes and the penetration depth of the holes into the filter. As previously mentioned the research on filter stain patterns was reviewed by Baker and Lewis (2001).^[187] They produced the following conclusion:

“We therefore conclude that the presence or absence of a distinctive bulls-eye staining pattern may not be related to the occurrence of vent blocking. The conclusions from studies that have used this technique are thus questionable.”

5.2.6 Mouth insertion depth studies

One approach to the assessment of the incidence of ventilation hole blocking by the smokers' lips has been the measurement of the position of the lips on the filter relative to the position of the ventilation holes. These are called mouth insertion depth studies and rely on the measurement of an imprint of the lips. This imprint can be produced by lipstick stains (Schulz 1974 (reported in Baker and Lewis (2001),^[187] or by staining for amylase (see Baker and Lewis (2001)^[187] for references) or ninhydrin (Porter and Dunn (1998),^[202] Baker Dixon and Hill (1998),^[188] and Hu et al (2003)^[192] in the dried saliva on the filters. Most of these studies show that the average mouth insertion depth for smokers is in the region of 10 mm to 11 mm from the mouth end of the cigarette. However Hu et al. (2003)^[192] reported an average insertion depth of 7,5 mm for Chinese smokers.

Baker and Lewis (2001)^[187] used mouth insertion depth distribution data from the Porter and Dunn (1998)^[202] study to estimate the relationship between the position of the vent holes on the filter and the degree of vent blocking. At a 9 mm vent hole placement around 40 % of smokers would have mouth insertion depths less than this value and would not cover any of the vent holes with their lips. At 11 mm placement 64 % of the smokers would have no contact with the vent holes and at 16 mm, 92 % of smokers would have no lip contact with the vent zone.

Baker, Dixon and Hill (1998)^[188] measured insertion depths using the ninhydrin staining method in UK smokers of a 4 mg ($n = 207$ smokers) and a 9 mg ($n = 202$) tar yield cigarette. They reported no evidence for vent zone coverage with lips for 1 553 from 1 852 (84 %) of filters from the 4 mg smokers and 1 585 from 1 821 (87 %) of filters from the 9 mg smokers.

Porter and Dunn (1998)^[202] examined 1 229 filters from ventilated Canadian cigarettes and by use of the ninhydrin method estimated that around 76 % of the filters showed no evidence of vent hole blocking.

Hu et al. (2003)^[192] examined the ninhydrin staining patterns on 1 742 filters randomly obtained from 6 Chinese cities and 1 037 filters from identified smokers in Kunming, China. They reported that 95 % of the filters analysed showed no indication of vent hole blocking.

Baker Dixon and Hill (1998)^[188] commented that the ninhydrin method could not be successfully used for all filters as around 11 % of the filters in their UK study had no distinct ninhydrin lip imprint. They hypothesized that this was caused by some smokers having dry lips which didn't leave saliva on the filters.

Kozlowski, O'Connor and Sweeney (2001)^[199] suggested that the lip imprint methods may underestimate the incidence of vent hole blocking because of the problems associated with dry lips.

5.2.7 Incidence of vent blocking conclusions

Based on the available data one can conclude the following:

- a) Responses to questionnaires about potential vent blocking may not reflect actual smoking behaviour. This may result in the data obtained from interviews and questionnaires being an over-estimate of the incidence of ventilation hole blocking.
- b) Data from the filter staining technique ("bulls-eye" method) in general indicate a higher incidence of vent blocking than does the data from the mouth insertion depth studies.
- c) The advocates of the mouth insertion methods (mainly Baker and colleagues) criticize the results from the "bulls-eye" staining studies. Advocates of the "bulls-eye" approach (mainly Kozlowski and colleagues) have criticized the findings from the insertion depth studies.

The apparent differences in the estimation of the incidence of vent blocking resulting from the various measurement approaches would cause problems if a new ISO method needed to consider the incidence of vent blocking among "average" groups of smokers. However, this is not an issue if vent blocking is to be incorporated into a new ISO smoking regime aimed at producing realistic maximum yields of tar, nicotine and CO likely to be obtained by humans smoking intensively. Clearly all studies indicate that vent blocking can occur in populations of smokers, thus some degree of vent blocking needs to be included in a "maximum yield" method.

5.3 The degree of vent hole blocking and its effect on yields obtained during human smoking

As mentioned in 4.2 fully or partially blocking the ventilation holes can have a marked effect on smoke yields when the cigarettes are smoked by a smoking machine. However, it is important to review data on the effects of vent blocking on yields obtained during human smoking.

There have been three approaches to measuring the effects of vent blocking on yields obtained by smokers as opposed to smoking machines. These are:

- a) Studies in which vent holes are deliberately blocked with tape, lips or fingers and smokers are cued to smoke the cigarettes to a fixed puffing regime (Kozlowski, Sweeney and Pillitteri (1996),^[197] Sweeney and Kozlowski (1998),^[206] and Zacny, Stitzer and Yingling (1986).^[208]
- b) As a) above but smokers who are allowed to smoke *ad libitum* (Sweeney, Kozlowski and Parsa (1999),^[207] Ayya et al. (1997),^[186] Reeves et al. (1997),^[203] StCharles and Hilton (1998),^[205] and Zacny et al. (1986).^[208]
- c) Comparisons of the estimated nicotine yields obtained by smokers who demonstrate some degree of vent blocking with those who show no vent blocking (Baker Dixon and Hill (1998).^[188]

5.3.1 Deliberate or artificial vent blocking during fixed puffing regime studies

Zacny et al. (1986)^[208] investigated the effects of artificially blocking 0,50 % and 100 % of the vent holes with tape on the increase in alveolar CO levels (CO boosts) following smoking a 1 mg tar yield cigarette. The puffing and inhaling patterns of 5 subjects were controlled i.e. 60 ml puff volume, 50 s inter-puff interval and 50 % Vital Capacity inhalation depth. They reported average CO boosts of + 0,8 ppm for the zero block condition, + 2,9 ppm for the 50 % and 7,1 ppm for the 100 % vent blocked condition.

Kozlowski et al. (1996)^[197] also measured the CO boosts resulting from smoking a 1 mg tar yield product with a) the vent holes unblocked, b) the vent holes maximally blocked by the smokers' lips, and c) 100 % of the vent holes blocked with tape. The 12 subjects smoked the cigarettes to a fixed regime of a 2 s duration puff taken every 50 s. They reported a mean CO boost for the unblocked condition of + 2,7 ppm, a boost of + 6,7 ppm for the lip blocked condition and a boost of + 12,9 for the 100 % blocked condition. In a follow up study Sweeney and Kozlowski (1998)^[206] examined the effects of vent blocking on the CO boosts resulting from smoking 10 mg tar yield cigarettes. They used the same controlled smoking regime as Kozlowski et al. (1996)^[197] and in this study the following vent block conditions were used:

- a) ventilation zones unblocked;
- b) 50 % of the vent zones blocked with adhesive tape;
- c) maximum lip blocking by the smokers i.e. the cigarettes were inserted into the mouth as far as necessary to cover as many vent holes as possible with the lips;
- d) maximum finger blocking by the smokers i.e. the smokers were asked to cover as many vent holes as possible by placing their thumb and forefinger over the vent zones while puffing on the cigarette.

The CO boosts for the 10 mg cigarette were essentially the same for all experimental vent block conditions. In other words, maximum vent blocking with lips or fingers or 50 % vent block with tape did not increase the CO boost of the 10 mg cigarette over and above that produced by the unblocked cigarette. However in the same study maximum finger blocking of the vent holes of a 1 mg cigarette produced a mean CO boost of a similar magnitude to that reported for maximal lip blocking by Kozlowski et al. (1996)^[197]

Kozlowski and coworkers concluded that maximal vent blocking with lips or fingers equates to 50 % vent block with tape and that such a vent block has a significant effect on the CO boost produced by highly ventilated 1 mg tar yield cigarettes but not of the less ventilated 10 mg tar yield cigarettes. This figure for lip blocking is in close agreement with the work of Roper 1997 (reported in Baker and Lewis (2001)^[187] who examined the lip imprints on filters left by smokers who had Nivea Cream on their lips for the study. This created a very sharp lip imprint image when the filter tipping paper was sprayed with iodine solution. Roper conducted the study using 52 subjects and 3 different ventilated cigarette brands. The vent zones of the cigarettes were positioned 11 mm from the mouth end of the cigarettes. The subjects took one puff from each cigarette in order to produce a clear lip imprint and they smoked 5 cigarettes of each type. Roper observed 735 clear imprints from a total of 780 filters. Of these 48 % showed some lip contact with the vent holes. In all these instances the vent hole coverage was partial with an overall mean of 27 % coverage of the vent zone and a maximum coverage of 50 % of the vent zone.

5.3.2 Deliberate or artificial vent blocking during ad libitum smoking behaviour studies

Zacny et al. (1986)^[208] included an ad libitum smoking condition in the study reported above. They observed an unblocked to blocked increase in CO boost of approximately 50 % for the 50 % vent block and approximately 107 % for the 100 % tape blocked 1 mg cigarettes. The corresponding % unblocked to blocked increases observed under the fixed smoking regime described previously were approximately 260 % for the 50 % blocked and 790 % for the 100 % blocked cigarettes.

Sweeney, Kozlowski and Parsa (1999)^[207] allowed two groups of smokers to smoke cigarettes ad libitum under unblocked, or lip or finger blocked conditions. As in previous studies by Kozlowski and colleagues CO boosts were measured. The first group of smokers (6 men and 6 women) smoked both a 1 mg and a 10 mg tar yield cigarette unblocked and then with maximal finger blocking. They observed no increase in the CO boost of the 10 mg cigarette during finger blocking. However, the CO boost was approximately doubled following the finger blocking of the 1 mg cigarette. The second group (12 females) smoked a range of cigarettes either unblocked or with maximal lip blocking. The results showed that maximal lip blocking produced an approximate 300 % increase in the CO boost of a highly ventilated (82,5 % filter ventilation) 1 mg cigarette, a 50 % increase in the CO boost of a 2 mg (66 % ventilated) cigarette, a 16 % increase in a 5 mg (56 % ventilated cigarette) and a < 10 % increase in an 8 mg (40 % ventilated) cigarette. These changes were not statistically significant for the 5 mg and 8 mg tar yield cigarettes.

Reeves et al. (1997)^[203] examined the effects on smoking behaviour of artificially blocking 50 % or 100 % of the vent holes of a range of ultra light and light cigarettes from the US market. Smoking behaviour

(puff numbers, volumes etc.) were measured by using an orifice type cigarette holder attached to the cigarettes and artificial vent blocking was achieved by using adhesive tape. Subsequent to this study, St Charles and Hilton (1998)^[20] analysed the spent filters from the Reeves et al. (1997) study and estimated the nicotine and tar yields produced by the cigarettes under the various ventilation block conditions. The following numbers of subjects and brands were used in the Reeves et al. study:

- Ultra Low-tar Low (ULL) 1 mg to 3 mg FTC tar yield — 10 subjects and 6 brands;
- Ultra Low-tar High (ULH) 4 mg to 6 mg FTC tar yield — 22 subjects and 12 brands;
- Lights 7 mg to 12 mg FTC tar yield — 21 subjects and 11 brands.

The increases in tar yields obtained when the artificially blocked cigarettes were smoked by machines and humans are summarized in Table 14.

Table 14 — Percentage increases in tar yields for the vent blocked cigarettes smoked by machine and humans

	Machine - 50 % block	Machine - 100 % block	Human - 50 % block	Human - 100 % block
ULL (1 mg to 3 mg)	+ 111 %	+ 372 %	+ 52 %	+ 114 %
ULH (4 mg to 6 mg)	+ 54 %	+ 109 %	+ 22 %	+ 33 %
Lights (7 mg to 12 mg)	+ 6 %	+ 19 %	+ 4 %	+ 2 %

The study revealed that the vent block induced increases in tar yields were considerably greater when the cigarettes were smoked by a smoking machine than when they were smoked by humans.

Dixon, Prasad and Kochhar (unpublished) recently conducted a vent blocking study using 4 commercially available 1 mg tar yield products. Three of these were from the German market and the other was a UK product. Twenty smokers were used and the cigarettes were smoked via an orifice type cigarette holder to provide puffing topography data. The cigarettes were smoked under three ventilation block conditions; ventilation zones open, 50 % blocked with tape, and 100 % blocked with tape. Each smoker smoked all cigarettes under all three vent block conditions and 2 replicates per subject were obtained for each vent block condition. Pre to post smoking exhaled CO boosts were measured and the spent filters were analysed and used to estimate tar and nicotine yields under the human smoking conditions. In addition the cigarettes were machine smoked (ISO parameters) under the zero, 50 % and 100 % vent blocked conditions and the tar, nicotine and CO yields were measured. The results from both the human and machine smoking procedures are shown in Table 15 below.

Table 15 — Ranges of % increases in tar, nicotine and CO yields resulting from 50 % or 100 % block of ventilation zones of four 1 mg tar yield cigarettes measured under machine and human smoking conditions

	Machine smoking 50 %	Machine smoking 100 %	Human smoking 50 %	Human smoking 100 %
Tar	177 % - 238 %	500 % - 629 %	31 % - 43 %	53 % - 84 %
Nicotine	160 % - 223 %	327 % - 427 %	25 % - 30 %	33 % - 54 %
CO	182 % - 270 %	259 % - 850 %	22 % - 26 %	36 % - 69 %

5.3.3 “Spontaneous” vent blocking and its effect on smoke yields during human smoking

In the previously mentioned mouth insertion depth study by Baker Dixon and Hill (1998)^[188] nicotine yields to the smokers were estimated from the analysis of the nicotine content of spent filters and knowledge of the nicotine filtration properties of the filters for the cigarettes used in the study. Plots of mouth insertion depths against nicotine yields were produced for the 197 smokers of a UK Light cigarette (9 mg tar yield) and 195 smokers of a UK Ultra Light cigarette (4 mg tar yield). There were wide variations in the nicotine yields obtained by the smokers of both types of cigarettes (range 0,4 mg

to 1,5 mg nicotine for the Light, and 0,1 mg to 1,0 mg for the Ultra Light cigarette) but there were no relationships between the distribution of nicotine yields and mouth insertion depths. If vent blocking had increased the yields of these cigarettes one would have expected to see higher nicotine yields for those smokers whose insertion depths were at or greater than the position of the vent zones than from those smokers whose insertion depths were less than the position of the vent zones. Consequently, Baker Dixon and Hill (1998)^[188] concluded that vent blocking was not associated with an increase in nicotine yields from 9 mg and 4 mg cigarettes during “normal” human smoking conditions.

5.3.4 Degree and consequences of vent blocking — Conclusions

One can draw a number of conclusions from the various studies aimed at assessing the degree of vent blocking and its influence on smoke yields under human smoking conditions. These include:

- a) The maximum area of the ventilation zones that can be covered by a smoker’s fingers or lips is approximately 50 % of the vent zone. This is an extremely important finding when one considers the role of vent blocking in a revised ISO test designed to give realistic maximal yields likely to be obtained by smokers. Clearly the 100 % ventilation blocking as used in the Canadian intense method is outside the realms of normal human smoking behaviour. One can argue that the 50 % vent blocking condition used in the Massachusetts intense smoking regime is a more realistic option for a revised ISO method.
- b) Vent blocking with lips, fingers or tape can have a marked influence on the yields of highly ventilated very low tar yield products (i.e. 1 mg to 2 mg tar yield) when smoked by humans. However vent blocking has minimal effects on “human smoke yields” for products with tar yields > about 5 mg and ventilation levels < about 60 %. This statement agrees with the comment by Kozlowski O’Connor and Sweeny 2001 in Chapter 2 of the NCI Monograph 13 i.e. “*Reviewing the literature vent blocking appears to be a significant mode of compensation for reduced yield among smokers of Lowest Tar yield cigarettes (e.g. 1 mg FTC tar) but not likely among most smokers of Light and Ultra Light cigarette brands*”.
- c) The effect of 50 % and 100 % blocking of vent zones on smoke yields is much greater during machine smoking than during actual human smoking conditions. Zacny et al. (1986),^[208] Reeves et al. (1997)^[203] and Baker Dixon and Hill (1998)^[188] reported that the main reason for this difference is the fact that vent blocking decreases human smoking behaviour parameters such as puff volume and number. This aspect of vent blocking is discussed in more detail in the following section.

5.4 The effect of vent blocking on puffing topography

Zacny et al. (1986)^[208] measured a number of puffing parameters during the ad libitum smoking part of their study. Five smokers of medium to high yield US cigarettes (average FTC tar yield 15,7 mg) smoked 1 mg tar yield cigarettes and their puffing topography was measured using an cigarette holder/flowmeter. Experimentally blocking 50 % or 100 % of the vent zones with tape produced a statistically significant reduction in both puff volume and puff number and a small increase in inter-puff interval compared with the vents open condition (see Table 16).

Table 16 — Mean values from Zacny et al. 1986 ad libitum smoking study

	Zero block	50 % block	100 % block	Significance
Puff number	13,2	11,1	9,2	$P < 0,01$
Puff volume (ml)	63,3	54,8	42,8	$P < 0,01$
Puff duration (s)	2,0	1,9	1,8	NS
Puff interval (s)	20,6	22,1	23,3	$P < 0,05$

Zacny et al. concluded that the decrease in puff volume following the vent block was caused by a large increase in pressure drop or “resistance to draw” of the cigarettes resulting from the covering of the vent holes. They reported that fully blocking the vent holes increased pressure drop from the open value of 92,5 mmWg to 184,4 mmWg.

Reeves et al. (1997)^[203] also observed marked vent block induced changes in puffing parameters in a vent block study conducted among regular smokers of US 1 mg to 3 mg (ULL), 4 mg to 6 mg (ULH) and 7 mg to 12 mg (Lights) tar yield cigarettes. These are shown in Table 17.

Table 17 — Mean puffing topography values from Reeves et al. 1997

ULL (1 mg to 3 mg) products — 10 smokers				
	Zero block	50 % block	100 % block	Significance
Puff number	9,5	8,5	7,1	$P < 0,1$
Puff volume (ml)	54,2	45,8	39,4	$P < 0,1$
Puff duration (s)	1,62	1,59	1,63	NS
Puff interval (s)	36,0	36,3	44,1	NS
Integrated puff pressure (cmWg.s)	40,3	45,1	55,0	NS
Max puff flow rate (ml/s)	55,2	46,6	38,9	$P < 0,01$
Total puff volume (ml)	501	380	262	$P < 0,01$
Lit cig. pressure drop (mmWg)	130	173	244	-
ULH (4 mg to 6 mg) products — 22 smokers				
	Zero block	50 % block	100 % block	Significance
Puff number	10,5	10,0	9,1	NS
Puff volume (ml)	48,9	43,4	37,9	$P < 0,05$
Puff duration (s)	1,81	1,79	1,76	NS
Puff interval (s)	29,8	30,6	31,1	NS
Integrated puff pressure (cmWg.s)	38,8	42,1	45,9	NS
Max puff flow rate (ml/s)	42,8	38,0	35,4	NS
Total puff volume (ml)	519	431	353	$P < 0,05$
Lit cig. pressure drop (mmWg)	139	169	212	-
Lights (7 mg to 12 mg) products — 21 smokers				
	Zero block	50 % block	100 % block	Significance
Puff number	11,1	11,6	10,9	NS
Puff volume (ml)	38,1	38,1	35,9	NS
Puff duration (s)	1,54	1,50	1,51	NS
Puff interval (s)	35,0	32,9	35,9	NS
Integrated puff pressure (cmWg.s)	31,9	33,5	35,9	NS
Max puff flow rate (ml/s)	38,5	39,2	37,0	NS
Total puff volume (ml)	420	435	386	NS
Lit cig. pressure drop (mmWg)	146	154	175	-

As can be seen from Table 17 the vent block conditions were associated with decreases in puff number, puff volume, total puff volume and maximum puff flow rate. Many of these decreases were statistically significant for the ULL and ULH products. However the vent block induced changes were much smaller and statistically insignificant for the Lights cigarettes. The Reeves et al. (1997)^[203] data for the ULL and ULH products are in general agreement with the results from Zacny et al. (1986)^[208] and confirm the hypothesis that the vent block induced changes in puff volume and puff flow rate appear to be driven by an increase in the pressure drop of the cigarettes following vent blocking.

Recently, Dixon, Prasad and Kochhar (unpublished) conducted a vent block study using 4 commercial 1 mg products and 20 smokers. It should be stressed that these were regular smokers of higher yield products unlike the Reeves et al. (1997)^[203] study which used regular smokers of the brands assessed. Brief details of this study were described in the previous section. The results from the puffing topography measurements are shown in Table 18.

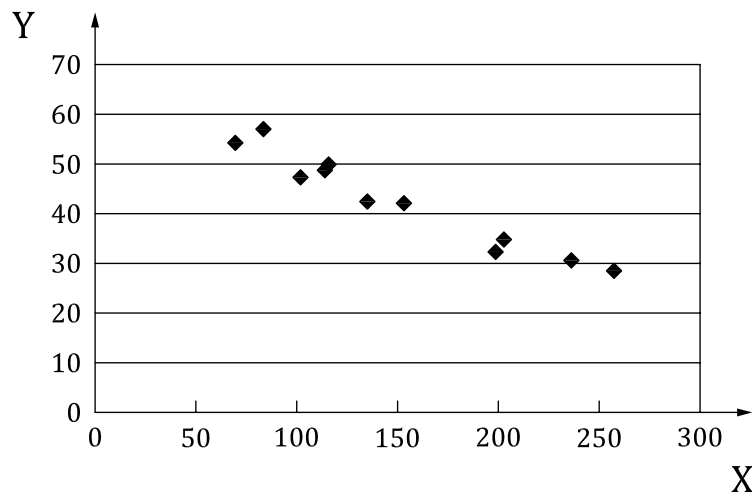
Table 18 — Mean, standard deviation, 10th and 90th percentiles for puffing parameters obtained from four 1 mg tar yield cigarettes under vents open, 50 % and 100 % vent block conditions

1 mg product A - 20 smokers - 2 replicates per condition				
	Zero block	50 % block	100 % block	ANOVA p
Puff number				P < 0,000 1
Mean	16,7	14,5	11,9	
SD	3,5	3,4	3,0	
90 th percentile	21	18	15	
10 th percentile	12,4	10	7,7	
Puff volume (ml)				P < 0,000 1
Mean	49,9	42,0	28,8	
SD	12,3	14,1	10,3	
90 th percentile	66,4	61,9	43,8	
10 th percentile	34,4	23,8	16,6	
Puff duration (s)				P = 0,97
Mean	1,72	1,72	1,75	
SD	0,47	0,59	0,62	
90 th percentile	2,20	2,24	2,33	
10 th percentile	1,29	1,16	1,11	
Total puff volume (ml)				P < 0,000 1
Mean	805	574	321	
SD	161	120	82	
90 th percentile	1006	730	440	
10 th percentile	572	437	234	
Integrated puff pressure (cmWG.s)				P < 0,000 1
Mean	32,7	37,0	42,4	
SD	9,1	13,8	16,9	
90 th percentile	46,4	57,5	64,0	
10 th percentile	21,8	19,3	23,6	
Max puff flow (ml/s)				p < 0,000 1
Mean	45,3	37,7	26,2	
SD	12,7	11,3	9,1	
90 th percentile	60,4	53,1	38,6	
10 th percentile	31,6	25,2	11,8	
Lit pressure drop (mmWg)	115	154	258	
1 mg product B - 20 smokers - 2 replicates per condition				
	Zero block	50 % block	100 % block	ANOVA p
Puff number				P < 0,000 1
Mean	18,3	14,9	12,9	
SD	4,2	3,4	3,0	
90 th percentile	24	20	17,3	
10 th percentile	13	11	9,0	
Puff volume (ml)				p < 0,000 1
Mean	54,3	47,6	32,2	
SD	12,8	12,8	10,9	
90 th percentile	68,9	64,8	46,8	
10 th percentile	36,6	30,6	19,1	
Puff duration (s)				p = 0,69
Mean	1,59	1,68	1,69	
SD	0,49	0,51	0,53	
90 th percentile	2,20	2,28	2,45	
10 th percentile	1,29	1,09	1,05	

Table 18 (continued)

Total puff volume (ml)				p < 0,000 1
Mean	962	680	392	
SD	215	134	93	
90th percentile	1193	760	508	
10th percentile	668	547	258	
Integrated puff pressure (cmWG.s)				p < 0,000 1
Mean	21,9	27,8	36,7	
SD	6,1	7,4	13,8	
90th percentile	29,5	37,8	55,2	
10th percentile	13,7	17,4	19,7	
Max puff flow (ml/s)				p < 0,000 1
Mean	50,2	42,8	29,8	
SD	13,9	11,9	10,7	
90th percentile	66,2	56,2	43,1	
10th percentile	32,9	28,9	14,9	
Lit pressure drop (mmWg)	70	102	199	
1 mg product C - 20 smokers - 2 replicates per condition				
	Zero block	50 % block	100 % block	ANOVA p
Puff number				p < 0,000 1
Mean	18,6	15,0	12,0	
SD	4,3	2,9	2,8	
90th percentile	25	19	16,3	
10th percentile	13,7	11,7	9	
Puff volume (ml)				p < 0,000 1
Mean	57,4	50,5	34,9	
SD	12,1	11,4	10,8	
90th percentile	70,1	63,8	46,9	
10th percentile	40,2	37,4	20,2	
Puff duration (s)				p = 0,88
Mean	1,74	1,72	1,70	
SD	0,47	0,46	0,46	
90th percentile	2,44	2,44	2,28	
10th percentile	1,19	1,19	1,21	
Total puff volume (ml)				p < 0,000 1
Mean	1052	740	395	
SD	277	155	82	
90th percentile	1392	880	495	
10th percentile	727	563	274	
Integrated puff pressure (cmWG.s)				p < 0,000 1
Mean	27,6	33,5	40,3	
SD	6,4	8,3	13,2	
90th percentile	36,8	42,8	58,4	
10th percentile	19,0	23,3	20,9	
Max puff flow (ml/s)				p < 0,000 1
Mean	51,6	45,6	31,7	
SD	14,1	11,1	9,9	
90th percentile	67,4	57,5	45,0	
10th percentile	34,6	32,4	17,6	
Lit pressure drop (mmWg)	84	116	203	

Partial or full block of the vent zones resulted in marked reductions in puff volume, total puff volume and puff flow rates for all four 1 mg products. The blocks were associated with large increases in lit cigarette pressure drop. This increase in pressure drop is the most likely explanation for the reductions in puff flow rates and puff volume. The relationships between cigarette pressure drop and puff volume for all four products and 3 vent block conditions are plotted in Figure 1.

**Key**

X lit pressure drop (mmWG)

Y puff volume (ml)

Figure 1 — Plot of lit pressure drop versus puff volume — Human smoking data from four 1 mg tar yield products under unblocked, 50 % and 100 % vent blocked conditions

5.5 The effect of vent blocking on puffing topography — Conclusion

The fact that vent blocking causes a reduction in puffing intensities (puff volume etc.) during human smoking is the most likely explanation for the differences between smoking machines and humans in the magnitudes of the vent block induced yield increases. Any potential effect of vent blocking on increasing smoke yields is to some extent offset by the reduction in smoking intensity during human smoking. However, this does not happen with machine smoking because the smoking machine takes a constant size puff irrespective of the vent block condition.

The observations on the influence of vent blocking on puffing parameters are important when one considers the role of vent blocking in a revised ISO smoking regime. One can argue that smokers can take very large puff volumes, especially on very low yield products, and thus a high puff volume should be incorporated into a new “maximum yield” smoking regime. One can also argue that because smokers can partially block the vent zones with lips or fingers some degree of vent blocking should be introduced into a “maximum yield” regime. However because of the interaction between cigarette pressure drop and puff volume a very high puff volume plus a high degree of vent blocking would not be a realistic “maximum yield” regime for smokers. For example the Canadian intense method specifies a 55 ml puff volume and 100 % vent block. The data from the study on 1 mg cigarettes indicates that the 90th percentiles for puff volumes under the 100 % vent block condition were 43,8 ml, 46,8 ml, 46,9 ml and 41,4 ml i.e. none of these approached the puff volume used in the Canadian intense method.

6 A review of cigarette butt lengths typically achieved by smokers when smoking their usual brand

6.1 Abstract

Cigarette butt length data have been reported in the peer-reviewed literature for many decades as one of many parameters that describe cigarette smoking behaviour. This document reviews butt length definitions for machine and human smoking conditions, provides a description of the relevance and impact of the butt length specification to machine-based analytical smoke yields and briefly examines butt length variability observed under conditions of actual use within a smoker population and for different cigarettes smoked by a single subject. Based on a comprehensive review of the human smoking

behaviour literature, worldwide cigarette butt length information has been summarized and compared to current ISO 4387 butt length specifications mandated for machine smoking.

In all countries studied, and for all types of cigarettes studied (filtered and non-filtered; relative high, mid, low, and ultra-low “tar” yields), smokers’ mean butt lengths exceed ISO 4387 machine-based standard butt lengths to varying degrees. On a worldwide basis, smokers’ mean butt lengths are 4,8 mm greater than the current ISO standard. In some countries, the differences between smokers’ and ISO 4387 butt lengths are minimal (e.g. + 1,9 mm and + 2,0 mm in the Netherlands and Belgium, respectively). In Japan the difference between smokers’ and ISO butt lengths is markedly greater (+ 15,8 mm).

Based on available data, it is recommended that the current ISO standard for butt length be incorporated into any proposal for a new robust and practical machine smoking regime that is more representative of smokers’ behaviour than the current International Standard ISO 4387 on machine smoking. In doing so, it is fully recognized that such a butt length standard, together with the more intensive puffing parameters anticipated for such a new smoking method, will likely over-estimate actual smoke yields achieved by smokers. Retaining the current butt length standard as part of any new proposed smoking method will provide a point of consistency between the two procedures (ISO 4387 and a new proposed smoking standard) and will provide a basis for comparing analytical data from all over the world.

6.2 Introduction

Cigarette butt length data have been reported in the peer-reviewed literature for many decades and for a variety of reasons. Butt length data have frequently been reported as one, of many, parameters that describe cigarette smoking behaviour.^[210-216] Butt lengths associated with different smoking populations have been studied as a possible explanation for differential disease risk among the smoking populations, e.g. the United Kingdom versus the United States.^[217] Butt lengths within a smoking population have also been studied to discern the effect of incremental taxation on smoking behaviour.^[218-221] Typically, such studies provide butt length data, but do not provide detailed information describing the cigarettes that were smoked. Therefore, without information regarding filter lengths, tipping lengths and overall cigarette lengths, it is not possible to relate the “raw” butt length data to butt lengths associated with current machine-based smoking standards.

Further, relationships between machine-generated smoke yields and the terminal butt length when smoking have been studied.^[222,223] The effect of different cigarette designs, i.e. tipping overwrap lengths, on butt length and machine-generated smoke yields has also been reported^[224].

Mindful of the scope and limitations of available butt length data, the objectives of this review were threefold, including:

- 1) Perform comprehensive literature searches to identify and collect all materials that appear relevant to human smoking butt length information.
- 2) Review and tabulate pertinent worldwide butt length data, with an emphasis on comparing reported findings relative to the ISO 4387 butt length specification mandated for machine smoking.
- 3) Based on these comparisons, recommend an appropriate butt length specification for a robust and practical machine smoking regime that is more representative of smokers’ behaviour than the current International Standard ISO 4387 on machine smoking.

In addition to these objectives, this document reviews the definitions of butt length for machine and human smoking conditions, provides a description of the relevance and impact of the butt length specification to machine-based analytical smoking and briefly examines the butt length variability observed under conditions of actual use within a smoker population and for different cigarettes smoked by a single subject.

6.3 Analytical smoking

Definition of cigarette butt length. When conducting analytical smoking (i.e. machine-based smoking to determine cigarette yields under standard conditions), a cigarette butt length is defined as the length of unburnt cigarette remaining at the moment when smoking is stopped.^[225] Identifying the “proper” butt

length for a cigarette under study is a critical parameter in the analysis process because the butt length establishes when the analytical smoking process is terminated. Currently, most commercially available smoking machines have some type of butt length sensing device that will terminate the puffing process when the specified butt length is achieved, even during mid-puff.

Importance of butt length to analytical smoking. Achieving the intended butt length during the analytical smoking process is critical to both measurement precision and accuracy. If the intended butt length cannot be consistently achieved, the measurement precision will be adversely affected because more, or less, of the cigarette will be consumed during smoking. Choice of the butt length will also affect the smoke yield observed for a cigarette. It is readily apparent that the amount of mainstream smoke yielded from a cigarette will generally increase as the butt length becomes shorter, assuming that the cigarette is puffed in a regular, periodic manner. Under such conditions, an observed increase in smoke yield occurs when a greater number of puffs is taken by the smoking machine. It has also been known for many decades that the amount of smoke contained in a puff increases as the cigarette decreases in length during the analytical smoking process.^[226] The increased amounts of smoke in the later puffs results from re-elution of material that has been deposited onto the tobacco column during the earlier puffs. Thus, the choice of a shorter butt length as the termination point for analytical smoking will potentially produce greater smoke yields due to a greater number of puffs being taken and puffs that are relatively greater in smoke yield, while a longer butt length specification will generally produce smaller yields for the same reasons.

Historical butt length standards for analytical smoking. There has been a variety of butt length standards applied for analytical smoking historically. In the past, standards have varied significantly from country to country and, potentially, from laboratory to laboratory in some countries. This is evident from 1973 survey data (Table 19) collected by a CORESTA Smoke Study Group.^[227] Survey responses from 16 countries regarding the cigarette butt length applied during analytical smoking indicated considerable variation in the approach to determining final butt length. As indicated in the Table, some reported butt length standards for filtered cigarettes were based on the cigarette filter length plus a portion of the tobacco rod, while others were based on the cigarette tipping length plus a portion of the tobacco rod. When the filter length served as the reference point, 8 mm of tobacco rod length was added to determine the analytical smoking butt length.

When the tipping length served as the product reference point, from 1 mm to 5 mm of tobacco rod length was added to that length to determine the analytical smoking butt length. Some countries had more than one standard, applying a particular standard based on the total length of the cigarette being tested (e.g. the United Kingdom). Several countries reported multiple standards (e.g. the Netherlands and Switzerland), suggesting a lack of consistency from laboratory to laboratory.

Table 19 — Results of 1973 CORESTA Smoke Study Group Survey of international machine-smoking practices (adapted from Reference[[227]])

Country from which replies have been received	Butt lengths (mm)		
	Non filter	Minimum for filter cigarettes	Filter cigarettes F = Filter T = Tipping
Belgium	23	23	F + 8 or T + 3
Finland	23	23	F + 8 or T + 3
France	23	23	F + 8 or T + 3
East Germany	23	23	23 or F + BifF > 15
West Germany	23	23	F + 8 or T + 3
Hungary	23	23	F + 8
Iran	23	23	F + 8
Luxembourg	23	23	F + 8 or T + 3
Netherlands (1 reply) a)	23	23	F + 8
(1 reply) b)	23	23	F + 8 or T + 3
South Africa	23	23	F + 8 or T + 3
Sweden	23	23	F + 8 or T + 1
Switzerland (3 replies) a)	23	23	F + 8 or T + 3
(1 reply) b)	23 or 1/3	23 or 1/3	F + 8 or T + 3
(1 reply) c)	23 or 1/3	23 or 1/3	F + 8 or T + 4
Thailand	23	23	F + 8
Tunisia	45	10	45 - 60 and 70
UK (all but 1) a)	20 if cig < 75	20	T + 3 if cig < 75
(1 reply) b)	25 if cig > 75	23	T + 5 if cig > 75
	23		F + 8 or T + 2
USA	23	23	T + 3

The magnitude of the effect caused by different butt length standards during analytical smoking was studied by Brunnemann, et al., in 1975.[222] In that study, a non-filtered and a filtered cigarette were each smoked according to the butt length standards reported by seven countries, together with one standard recommended for international use. Countries from North America, Europe and Asia were represented. A consistent puff volume, puff frequency and puff duration were applied for all analytical smoking.

As summarized in Table 20, large differences in wet total particulate matter (wet TPM) yields were observed for the non-filtered cigarette for a butt length range of 15 mm to 30 mm. Wet TPM yields from 49,9 mg to 33,2 mg were found, with the greater yield achieved with the shorter butt length. Wet TPM yields from approximately 36 mg to 39 mg were found for the non-filtered cigarette when it was smoked to a 23 mm butt length. Nicotine yields also tended to increase as butt length decreased, with nicotine yield from approximately 1,7 mg to 2,1 mg observed for the non-filtered cigarette.

Smaller wet TPM and nicotine yield differences were found for the filtered cigarette. For example, wet TPM values of approximately 21 mg to 22 mg and 26 mg were found for butt lengths of overwrap + 5 and overwrap + 1, respectively. Similarly, nicotine yields of 1,32 mg and 1,42 mg were found for butt lengths of overwrap + 5 and overwrap + 1, respectively.

From these data, it is evident that a single butt length standard is necessary if consistent smoke yield data are to be obtained from different laboratories and from different countries.

6.4 Current international standard for analytical smoking

The current international standard for the machine smoking of cigarettes, ISO 4387, requires either a final butt length of filter length + 8 mm or tipping length + 3 mm, whichever is longer, when conducting analytical smoking of filter-tipped cigarettes.^[229] Non-filtered cigarettes are smoked to a final butt length of 23 mm. The standard was last revised in 2000.

Table 20 — Comparison of standard methods circa 1975 (adapted from Brunnemann, et al., Reference^[222])

Country	Puffing parameters			Butt length (mm)		85 mm non-filtered cigarette		85 mm filtered cigarette	
	Puff volume (s)	Puff interval (s)	Puff duration (s)	Plain	Filter ^a	Wet TPM yield (mg/cig.)	Nicotine yield (mg/cig.)	Wet TPM yield (mg/cig.)	Nicotine yield (mg/cig.)
Austria	35	60	2	15	OW + 5	47,9	2,09	20,8	1,32
Canada	35	60	2	30	30 (OW + 3)	34,4	1,83	21,9	1,35
France	35	60	2	23	OW + 3	38,9	1,87	20,3	1,32
Japan	35	60	2	30	30 (OW + 3)	33,2	1,79	21,6	1,37
W. Germany	35	60	2	23	OW + 1	37,4	1,73	25,7	1,42
UK	35	60	2	20	OW + 5	40,5	1,92	22,3	1,32
USA	35	60	2	23	OW + 3	36,8	1,86	22,3	1,35
CORESTAb	35	60	2	23	F + 8	36,5	1,84	25,1	1,31

^a OW = Overwrap, F = Filter
^b CORESTA = Centre de Coopération pour les Recherches Scientifiques relatives au Tabac

6.5 Conditions of consumer use

6.5.1 General

When cigarettes are smoked by a smoker, the cigarette butt length is defined as the length of unburnt cigarette remaining at the moment when the cigarette stops smoldering. The cigarette may stop smoldering because it has been “snubbed-out” by the smoker or after free smoldering in an ashtray or other location for a period of time beyond the point in time that active smoking has ended. Therefore, one limitation of butt length data collected under conditions of consumer use is that the cigarette butt length does not necessarily indicate the proportion of the tobacco rod that was consumed by the smoker. This fact has been recognized for many decades. For example, in 1958 Hammond wrote:^[217]

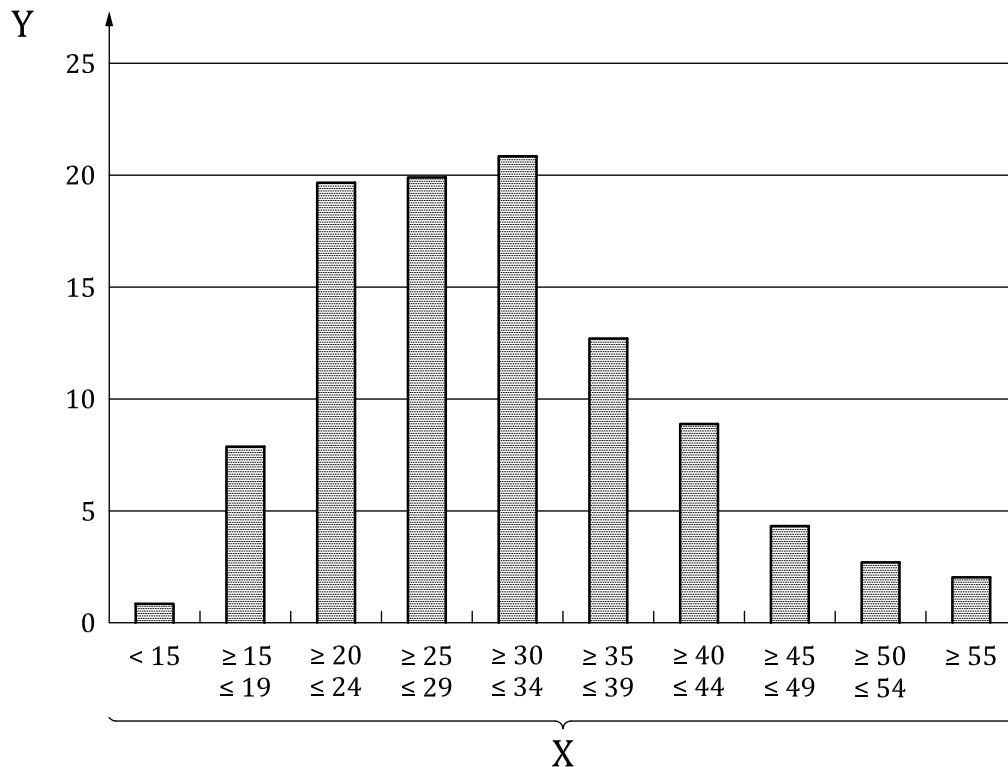
“... it is questionable whether the length of a discarded cigarette butt is a reliable index of the amount of smoke which was drawn into the mouth of the smoker. For example, lighted cigarettes are sometimes left to burn out in the ash-tray or on the ground. Furthermore, much of a cigarette may burn up while being held in the hand or left in an ash-tray between puffs. Thus a short butt does not necessarily indicate that most of the potential smoke from the cigarette was drawn into the mouth of a smoker. On the other hand, a long butt is sure proof that the smoker failed to avail himself of a large proportion of the potential smoke.”

6.5.2 Variability in butt length data under conditions of consumer use

It has been well established that smoking behaviour is quite variable. The puff volume, puff duration and interpuff interval that smokers apply to the cigarette while smoking can, and does, vary from puff to puff and from cigarette to cigarette. Further, significant variability in puffing behaviours has been observed from one smoker to the next.

Like puffing behaviours, the point at which a smoker stops smoking their cigarette is known to vary from cigarette to cigarette and from smoker to smoker. For example, Hammond collected data on cigarette butt lengths in four major cities in the United States in 1958.^[217] A total of 4 283 cigarette butts were

collected from homes, offices, restaurants, sidewalks, stations and parks and each was measured to determine length. The average length for all butts collected was 30,9 mm, with similar lengths observed for filtered and non-filtered cigarettes (31,0 mm and 30,7 mm, respectively). Based on the lengths of filtered and non-filtered cigarettes sold in the US in 1958, Hammond concluded that about 38 % of each filter-tipped cigarette and 41 % of each non-filtered cigarette were discarded without smoking. The distribution of butt lengths that he observed in his study is found in [Figure 2](#).

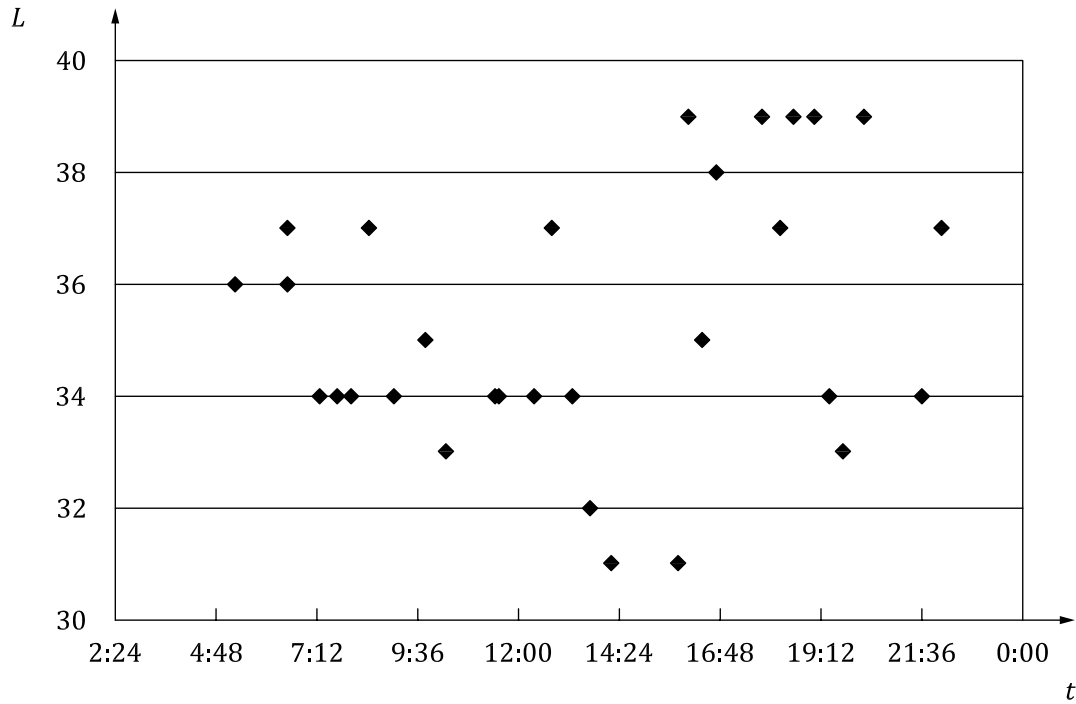


Key

- X cigarette butt length (mm)
Y percentage observed

Figure 2 — Distribution of cigarette butt lengths observed by Hammond in the United States in 1958

More recently, a study of US smokers conducted by R.J. Reynolds Tobacco Company beginning in 2002 has investigated cigarette to cigarette butt length variation.^[229] [Figure 3](#) provides an indication of inter-cigarette butt length variability for an individual smoker during the course of a 24 h period.



Key
t time of day
L cigarette butt length (mm)

Figure 3 — Variability in observed cigarette butt lengths during the day for a subject smoking their usual low “tar” cigarette brand

6.6 Comparison of butt lengths observed under conditions of use with machine-based smoking standard butt lengths

6.6.1 Methods

Three approaches were used to identify and collect relevant information on the subject of butt length: (1) articles or references available to the general public were identified by searching two internet online databases (with the search strategy of “butt AND length”), PubMed, National Library of Medicine (www.ncbi.nlm.nih.gov), and Legacy Tobacco Documents Library, University of California, San Francisco (www.legacy.library.ucsf.edu); (2) retrieved articles were reviewed for associated citations in their respective reference sections; and (3) relevant internal tobacco company reports were contributed from the ISO/TC 126 tobacco company participants.

Each retrieved article or report was reviewed to determine document acceptability. To be acceptable, the data contained in the document had to include enough information to establish (a) total butt lengths and (b) the differences of these values relative to ISO 4387 butt length specifications (i.e. filter tipping length + 3 mm for filtered cigarettes, or 23 mm for non-filtered cigarettes). Additionally, data resulting from subjects smoking their usual brand of cigarettes were considered acceptable; whereas, research that described cigarette brand “switching” studies, i.e. subjects not smoking their usual brand, were not considered acceptable.

Results. Based on the document selection criteria described above, 24 documents were identified as having possible utility. Of these, only 8 documents contained sufficient information to conform to the selection criteria. These documents are listed in the bibliography under “Specific references for [Clause 6](#) — References and documents that provided data used in butt length review”. The remaining 16 documents identified (listed in the bibliography under “Specific references for [Clause 6](#) — References and documents that did not provide useful data for the butt length review) generally lacked

either (a) pertinent data or (b) a direct or indirect reference to the cigarette sample tipping paper length. As such, the available data could not be used for comparisons to the ISO standard. The 8 documents that did contain useful butt length data were all tobacco industry-related studies, which in some cases were conducted in multiple countries. Collectively, these 8 studies accounted for 37 789 butt length measurements, in 11 separate countries, and spanning a time-range from 1979 to 2004 (25 years).

All acceptable butt length study data are compiled chronologically in Table 22, with the following information presented (when available): country; year data collected; product type; ISO/FTC tar yield; number of subjects; number of butts measured; experimental setting; mean butt length, standard deviation (SD) or standard error (SE), 90th and 10th percentiles; mean differences in butt length relative to ISO 4387, SD or SE; and references. Select information is also summarized in Table 21, which provides non-weighted mean differences in butt lengths relative to the ISO standard in various countries.

Overall, mean butt length ($n = 37\ 789$) was found to be 35,7 mm, with a corresponding mean difference with the ISO standard of + 5,2 mm (Table 21). However, since a small portion of this data set may not be a true representation of smokers' behaviour, data from the reports having a "study setting" of either "laboratory" or "ITL (industry) employees smoking in their offices" were removed from the analysis. This adjusted "overall" mean butt length ($n = 34\ 560$) was only slightly changed and found to be 35,5 mm, with a corresponding mean difference with the ISO standard of + 4,8 mm. Accepting the adjusted data as the most accurate, on average, smokers extinguish their cigarettes 4,8 mm longer than the length used in the ISO standard. It is noted that this value is conservatively biased (in some studies), in that, an undeterminable number of discarded butts may continue to burn for some unknown amount of time before self-extinguishment.

In studies that documented cigarette "tar" yields, no correlation in smokers' butt lengths and ISO/FTC "tar" yields were apparent (Table 22), with the possible exception in the MMV study where butt lengths tended to be longer the higher the product yield.^[230]

**Table 21 — Summary of worldwide butt length data by country and experimental setting
(Filtered and non-filtered cigarettes / All tar yields)**

Country	No. reports	No. butts/ Study	Mean butt length (mm)	Mean difference from ISO (mm)	Study setting	Reference
Belgium	1	930	28,9	+2,0	Unrestricted	CECCM, 1991
Brazil	1	200	40,2	+3,7	Unrestricted	CECCM, 1991
Canada	1	1059	nd	+9,6	ITL Employees	ITL, 1979
Denmark	1	1052	40,2	+3,7	Unrestricted	CECCM, 1991
France	1	1886	29,0	+3,7	Unrestricted	CECCM, 1991
Germany	2	1093	35,9	+6,5	Unrestricted	CECCM, 1991
		980	34,1	+5,1	Unrestricted	ITL, 2005
Japan	1	1152	50,8	+15,8	Restaurant Survey	CORESTA, 2003
Nether- lands	1	1455	26,9	+1,9	Unrestricted	CECCM, 1991
Spain	1	850	31,8	+5,0	Unrestricted	CECCM, 1991
UK	4	1525	33,3	+3,3	Unrestricted	CECCM, 1991
		7204	35,0	+2,0	Unrestricted	BAT & ITL, 1998
		1000	32,6	+4,6	Unrestricted	ITL, 2005
		1600	39,7	+9,2	Laboratory	Dixon/WG, 2005
^a "Adjusted all data" excludes data in shaded areas pertaining to tobacco company employees or laboratory "study settings."						

Table 21 (continued)

Country	No. reports	No. butts/ Study	Mean butt length (mm)	Mean difference from ISO (mm)	Study setting	Reference
USA	2	570	35,0	+2,8	Laboratory	MMV, 2004
		4705	36,5	+4,4	Unrestricted	MMV, 2004
		10528	41,8	+5,3	Unrestricted	St, Charles, 2004
All data	8	37789	35,7	+5,2	All	na
Adjusted all data ^a	5	34560	35,5	+4,8	Unrestricted/ Restaurant Survey	na

^a "Adjusted all data" excludes data in shaded areas pertaining to tobacco company employees or laboratory "study settings."

6.6.2 Discussion

Review and analysis of worldwide butt length data demonstrates that in all countries studied, and for all types of cigarettes studied (filtered and non-filtered; relative high, mid, low, and ultra-low tar yields), smokers' mean butt lengths exceed ISO 4387 machine-based standard butt lengths to varying degrees. In some countries, the differences between smokers' and ISO 4387 butt lengths are very similar (e.g. + 1,9 mm and + 2,0 mm in the Netherlands and Belgium, respectively). In Japan the difference between smokers' and ISO butt lengths is markedly greater (+ 15,8 mm).

The apparent net effect of smokers' behaviour in terms of butt length would indicate that the current ISO standard method overestimates mainstream smoke yields, if butt length alone is the principal factor that determines yield. Further, this overestimation appears culturally dependent, perhaps because of the types of cigarettes sold in a particular country or the average smokers' behaviour common to that particular country. However, since actual mouth-level intake of cigarette smoke can be affected by multiple factors, including cigarette design and smokers' puffing behaviours, the relative contribution of cigarette butt length, isolated from these other parameters, to mainstream smoke yield is equivocal at best.

In summary, based on available pertinent data, the following can be concluded:

- On a worldwide basis, smokers' mean butt lengths are greater in all countries studied (+ 4,8 mm; ranging from + 1,9 mm to + 15,8 mm) relative to the current ISO standard.
- Smoking behaviour pertaining to butt lengths appears culturally dependent by country, while smokers' butt lengths appear to be generally independent of ISO/FTC tar yield.

6.7 Recommendation for an appropriate butt length specification more representative of smokers' behaviour

In principle, the butt length specification for a robust and practical machine smoking regime that is more representative of smokers' behaviour than the current International Standard ISO 4387 on machine smoking can take one of three forms: (a) butt lengths that are shorter than the current standard, (b) butt lengths that are equivalent to the current standard or (c) butt lengths that are longer than the current standard. Available data uniformly suggest that a longer butt length standard than is specified by ISO 4387 is more representative of smokers' behaviour worldwide. However, available data also indicate that smokers in some countries achieve butt lengths similar to the current ISO standard, while smokers in certain other countries smoke cigarettes to much longer butt lengths. When these data are considered together with the facts that (a) considerable variability in butt lengths exists within a given country's smoking population from one smoker to the next, and (b) variability exists for a given smoker potentially from one cigarette to the next, it becomes clear that no single butt length standard is completely adequate

to better represent smokers' worldwide behaviour. As such, the comments of Wynder and Hoffmann from 1967 on the subject of analytical smoking butt length seem relevant still today:[230]

“Again, it cannot be the objective of the tobacco scientist to duplicate human smoking patterns, but rather, to arrive at standard values acceptable to the majority of investigators and, therefore, permitting comparison of analytical data from all over the world.”

Therefore, it is recommended that the current ISO standard for butt length be incorporated into any proposal for a new robust and practical machine smoking regime that is more representative of smokers' behaviour than the current International Standard ISO 4387 on machine smoking. In doing so, it is fully recognized that such a butt length standard, together with the more intensive puffing parameters anticipated for such a new smoking method, will likely over-estimate actual smoke yields achieved by smokers. Retaining the current butt length standard as part of any new proposed smoking method will provide a point of consistency between the two procedures (ISO 4387 and a new proposed smoking standard) and will provide a basis for comparing analytical data from all over the world.

Table 22 — ISO/TC 126 - Butt length analysis

Country	Year data Collected	Product types	ISO/FTC "tar" yield range (mg/cig.)	Number of subjects	Number of cigarette butts	Setting; Lab/ Unrestricted/ Other	Butt lengths (mm)				Diff. from ISO 4387 (mm)			Source (Ref. No. in Bibliography(231-238))
							Mean	Std. dev.	Std. err.	90th percentile	10th percentile	Mean	Std. dev.	
Canada	1979	High Tar	= 16	? (= 20)	232	ITL employees	nd				+9,9			ITL 1979 (1)
		Mid Tar	8-15	? (= 20)	569	ITL employees	nd				+9,4			
		Low	1-7	? (= 20)	258	ITL employees	nd				+9,6			
Belgium	1991	KS FF		29	290	unrestricted	30,9			0,7	+1,5		0,7	CECCM 1991 (2)
		KS Low		16	160	unrestricted	32,4			0,5	+0,2		0,7	
		Reg		28	280	unrestricted	27,4			0,6	+4,4		0,6	
Denmark	1991	Plain KS		20	200	unrestricted	25,0			1,0	+2,0		1,0	
		100s		25	210	unrestricted	35,4			0,7	+2,4		0,7	
		KS FF		52	432	unrestricted	31,8			0,5	+3,8		0,5	
France	1991	Plain KS		21	189	unrestricted	25,5			1,1	+2,5		1,1	
		Plain Reg		24	221	unrestricted	25,7			0,7	+2,7		0,7	
		KS FF		78	762	unrestricted	33,8			0,5	+4,5		0,5	
Germany	1991	Reg		25	245	unrestricted	26,8			0,7	+3,8		0,7	
		Plain Reg		89	879	unrestricted	25,8			0,5	+2,8		0,5	
		100s		20	185	unrestricted	41,2			1,0	+8,2		1,0	
UK	1991	KS FF		40	355	unrestricted	36,0			0,5	+7,0		0,5	
		KS Low (29 mm)		24	229	unrestricted	37,5			0,5	+8,5		0,5	
		KS Low (33 mm)		15	136	unrestricted	36,4			1,0	+3,4		1,0	
Netherlands	1991	Plain Reg		20	188	unrestricted	28,5			1,1	+5,5		1,1	
		100s		61	604	unrestricted	35,2			0,5	+2,0		0,5	
		KS UM		49	470	unrestricted	32,1			0,6	+3,5		0,6	
Spain	1991	KS Low		48	451	unrestricted	32,5			0,6	+4,5		0,6	
		KS FF		110	1089	unrestricted	32,1			0,3	+3,0		0,3	CECCM 1991 (2)
		Plain KS		17	170	unrestricted	24,5			0,9	+1,6		0,9	(cont)
Spain	1991	Plain Reg		20	196	unrestricted	24,2			0,8	+1,2		0,8	
		KS FF-Bik		40	400	unrestricted	30,3			0,8	+5,4		0,8	

Table 22 (continued)

Country	Year data Collected	Product types	ISO/FTC "tar" yield range (mg/cig.)	Number of subjects	Number of cigarette butts	Setting: Lab/Unrestricted/Other	Butt lengths (mm)						Diff. from ISO 4387 (mm)			Source (Ref. No. in Bibliography ^[231-238])	
							Mean	Std. dev.	Std. err.	90th percentile	10th percentile	Mean	Std. dev.	Std. err.			
		KS FF-Bld		45	450	unrestricted	33,2		0,5				+ 4,5		0,5		
Japan	1996	full range	1-17		1152	restaurant	50,8	8,0		85 max.	28 min.		+ 15,8			JTI 2003 (3)	
UK	1998	FF	12,0	255	2501	unrestricted	35,0	3,6		39,2 max.	31,7 min.		+ 2,0	3,6		BAT & IITL 1998 (7)	
		L	9,3	242	2372	unrestricted	36,0	4,1		40,5 max.	32,0 min.		+ 3,0	4,1			
		Ult	0,4	237	2331	unrestricted	34,1	3,3		38,2 max.	31,0 min.		+ 1,1	3,3			
UK	2001	FF	11	100	400	lab	37,2	3,6		42,0	33,4		+ 9,2			BAT 2005 (4)	
		M	5	100	400	lab	38,7	3,7		42,8	34,3		+ 10,7				
		L	3	100	400	lab	40,8	4,0		46,0	35,4		+ 7,8				
		Ult	1	100	400	lab	41,9	4,4		48,5	36,3		+ 8,9				
Brazil	2004	M	6	50	100	lab	38,7	8,3		50,7	31,0		+ 3,7				
		Ult	1	50	100	lab	41,7	7,4		52,8	34,0		+ 3,7				
USA	2004	FF	13-18	11	110	lab	35,3	5,1		42,0	29,0		+ 6,7	5,8		RJRT 2004 (5)	
		L	9-11	24	240	lab	35,2	4,5		41,0	30,0		+ 1,2	4,5			
		Ult	4-5	22	220	lab	34,5	4,2		40,0	30,0		+ 0,5	4,2			
		FF	13-18	11	846	unrestricted	35,7	6,7		45,0	28,0		+ 7,3	6,8			
		L	8-11	24	2005	unrestricted	36,4	5,3		43,0	30,0		+ 2,4	5,3			
		Ult	4-5	22	1854	unrestricted	37,6	5,0		44,0	31,0		+ 3,6	5,0			
USA	2004	100	1	50	641	unrestricted	42,3	5,7					+ 3,3			St Charles 2005 (6)	
		100	1	49	662	unrestricted	44,5	8,0					+ 5,5				
		KS	1	49	658	unrestricted	40,3	7,3					+ 5,3				
		100	3	48	619	unrestricted	43,8	7,0					+ 5,8				
		100	5	49	680	unrestricted	43,9	7,9					+ 5,9				
		100	5	44	687	unrestricted	44,4	7,2					+ 5,4				
		100	6	48	682	unrestricted	42,4	6,2					+ 3,4				
		100	6	49	582	unrestricted	43,1	6,1					+ 3,1				
		100	9	36	266	unrestricted	40,1	7,7					+ 5,1				

Table 22 (continued)

Country	Year data Collected	Product types	ISO/FTC "tar" yield range (mg/cig.)	Number of subjects	Number of cigarette butts	Setting: Lab/ Unrestricted/ Other	Butt lengths (mm)				Diff. from ISO 4387 (mm)			Source (Ref. No. in Bibliography(231-238f))
							Mean	Std. dev.	Std. err.	90th percentile	10th percentile	Mean	Std. dev.	
		100	9	49	657	unrestricted	43,8	7,2			+ 4,8			
		KS	9	49	552	unrestricted	39,2	7,3			+ 5,2			
		KS	10	50	716	unrestricted	45,9	8,1			+ 10,9			
		KS	11	49	717	unrestricted	44,7	7,4			+ 9,7			
		100	11	48	538	unrestricted	44,4	7,3			+ 5,4			
		100	14	47	600	unrestricted	42,1	6,0			+ 3,1			
		KS	16	47	651	unrestricted	31,3	6,3			+ 2,3			
		KS	18	45	620	unrestricted	34,4	8,5			+ 6,4			
UK	2005	FF	10,0	50	1000	unrestricted	32,6	3,5			+ 4,6	3,5		ITL 2005 (8)
Germany	2005	FF	10,8	49	980	unrestricted	34,1	3,3			+ 5,1	3,3		
			Total (all reports) =	Total (all reports) =	37789	Mean (all reports) =	36,1				+ 4,9			

7 Cigarette smoking and nicotine intake

7.1 General

Nicotine is the major determinant of tobacco use and addiction. The nicotine content of cigarettes varies significantly depending on tobacco blend and the country of origin. However the amount of nicotine in mainstream smoke is determined by cigarette design, including tobacco type, and human smoking behaviour. This review focuses on nicotine intake (mouth level exposure) as it relates to the published data on human smoking behaviour, and discusses the adequacy of the ISO/FTC method to inform on human exposure. A large body of evidence demonstrates changes in smoking patterns when smokers switch from smoking cigarette brands with higher to lower machine determined nicotine yields. Repeatedly, a pattern of compensation is documented suggesting that smokers regulate nicotine intake to sustain their addiction. No single smoking regime can fully capture human smoking behaviour, the existing ISO/FTC regime seriously underestimates the amount of nicotine that a smoker is exposed to and, does so in a systematic fashion, the degree of underestimation increasing as ISO/FTC yields decrease. The ISO/FTC ratings do not necessarily parallel actual nicotine content in tobacco and many light cigarettes contain as much nicotine as their regular counterparts or more. The application of more intense machine-smoking regimes, as specified by the Massachusetts and Health Canada protocols or protocols that mimic human puffing behaviour produces significantly higher values for the amount of nicotine in mainstream smoke than measured by the ISO/FTC regime. The objective of this review is to summarize the scientific evidence on factors that influence nicotine intake delivery and to recommend machine-smoking protocol(s) for determination of smoke constituents, including, nicotine in order to better understand cigarette design and the variation in constituents generated under the range of smoking conditions used by smokers. Therefore, both machine parameters that reflect common use as well as machine parameters that reflect the upper range of human cigarette smoking in order to understand the range of deliveries for cigarette products are needed.

7.2 Introduction

Nicotine is the major determinant of tobacco use and addiction.^[255,256] It is delivered to the cigarette smoker predominantly by inhalation of mainstream smoke. Different types of tobacco contain different amounts of nicotine; in general, the highest levels are found in burley tobacco, the next highest in flue-cured, and lowest levels in oriental tobacco. The nicotine content of cigarette tobacco varies from about 7,2 mg to 23,5 mg per gram.^[256,257] On average and based on intake studies, the mainstream smoke of one cigarette yields just over 1 mg of nicotine (range 0,5 mg to 2,0 mg)^[255]; in chronic smokers, the total daily intake appearing to be relatively constant over time.^[258-261] However, such intake shows great individual variation, is largely independent of the machine-determined yields, and can significantly increase (up to threefold or more) in response to restricted nicotine availability.^[257,262] Traditionally, the ISO/FTC machine-smoking method has been used to report on the amount of nicotine exiting the cigarette.^[263] However, many studies have demonstrated that the ISO/FTC machine-smoking method does not reflect human smoking behaviour^[256] and that there is no relationship between brand ISO/FTC nicotine yield and nicotine content of tobacco.^[255,256,259] The ISO/FTC ratings do not necessarily parallel actual nicotine content and many light cigarette brands use tobacco with higher concentration of nicotine than the “full flavor” counterparts. In order to better understand cigarette smoke emissions under conditions which better approximate human smoking behaviour, standard smoking conditions have been compared with different nonstandard methods involving variable puff volume, puff duration, and interval between puffs.^[264] The studies demonstrated that up to 95 % of the variation in tar yield per cigarette could be explained by variation in the total volume of smoke drawn per cigarette. This obviously affects other constituents of the cigarette smoke, including nicotine and other toxic and genotoxic agents. In a recent study by Djordjevic and coworkers, the puffing characteristics of adult cigarette smokers were determined and the yields of tar, nicotine, and two lung carcinogens were measured in the mainstream smoke generated from each individual’s brand by mimicking his or hers smoking patterns using a piston-type smoking machine. It was reported that smokers of low- (<0,8 mg nicotine by FTC method) and medium yield (0,9 mg to 1,2 mg) brands received 2,5 and 2,2 times more nicotine than the yields obtained by the FTC method.^[257,262]

This review summarizes published data on nicotine content in mainstream cigarette smoke and the extent that compensation takes place upon changing the smoking conditions or cigarette brands.

7.3 Nicotine metabolism

Understanding the metabolism of nicotine has been useful to understand the effect of nicotine on the human body and in which ways the amount of its intake influences human behaviour in cigarette smoking and to have better assessment of the nicotine intake (amount delivered to the smoker) and uptake (amount absorbed by the body).[263] Nicotine can be measured directly in blood and it is excreted in urine as nicotine (9,8 %) as well as nicotine glucuronide (4,2 %), nicotine-1-N'-oxide (4,4 %), and nornicotine (0,4 %).[255] However, in many situations it is preferred to estimate nicotine intake by measuring its major metabolite, cotinine.[259,266] The latter has a longer half-life (16 h versus 2 h for nicotine) and its level shows less variation throughout the day than that of nicotine. About 70 % to 80 % of nicotine is metabolized to cotinine (13 %) and other cotinine metabolites [trans-3'-hydroxycotinine (33,6 %), cotinine glucuronide (12,6 %), trans-3 hydroxycotinine glucuronide (7,4 %), cotinine-N-oxide (2,4 %), and norcotinine (2 %)].[255] The measurement of cotinine gives a good estimate of the daily intake of nicotine. For example, on average, a cotinine level of 300 ng/ml corresponds to a daily nicotine intake of about 24 mg.[255,266] Measurements of urinary excretion of nicotine and its metabolites are also useful to measure the amount of nicotine taken in by a smoker per day.[266,267] Moreover, saliva cotinine highly correlates with plasma cotinine and has been used for the same purpose.[255] The analysis of these biochemical markers has been very useful in measuring nicotine uptake and the effect of brand switching, often expressed as degree of compensation.[259]

7.4 Nicotine intake and switching studies

D.E. Creighton defined compensation as the “subconscious changes made to the smoking pattern by a smoker in an attempt, which may or may not be successful, to equalize the deliveries of products which have different deliveries when smoked by machine under standard conditions.” A number of studies have been conducted to study the effect of switching on nicotine uptake:

- 1) **Short-term experimental switching studies:** In these studies, smokers were asked to switch to brands of higher or lower machine-determined yield. Their resultant nicotine uptake was compared to that from the usual brand they smoked. Results demonstrated that smokers compensate for reduced nicotine deliveries; the extent of this compensation ranged from 20 % to 100 %. This compensation was accomplished through smoking more cigarettes per day and by taking in more tobacco smoke per cigarette when compared to smoking machine predictions.[268-271]
- 2) **Long-term experimental switching studies:** In these studies, the extent of compensation based on nicotine intake was about 80 % in smokers who were switched from higher to lower yield cigarettes for periods exceeding few weeks. Compensation occurred primarily by increasing the intensity with which cigarettes were smoked. Increasing the number of cigarettes smoked had an additional variable contribution.[272-276]
- 3) **Studies of smokers smoking self-selected brands:** These studies are particularly valuable for investigating the association of brand yield with intake, because smokers have chosen the brands that they are happy to smoke. The biomarkers investigated in these studies included markers of nicotine exposure such as blood nicotine, blood or saliva cotinine, or urinary nicotine metabolites. There were some differences in nicotine exposure when high- and low-yield brands were compared. However, in 14 studies, there were weak or no significant correlations between nominal ISO/FTC yields of cigarettes and nicotine intake (Table 23)[259] Thus, ISO/FTC nicotine ratings are extremely poor predictors of actual nicotine intake and the ISO/FTC method underestimates human exposure to nicotine. This is especially true in smokers of low-yield cigarettes. In a study by Jarvis and coworkers of 2 031 adult smokers of manufactured cigarettes surveyed in the 1998 Health Survey for England, nicotine intake per cigarette was about eight times greater than machine-smoked yields at the lowest deliveries (1,17-mg estimated nicotine intake per cigarette from brands averaging 0,14-mg delivery from ISO machine smoking) and 1,4 times greater for the highest yield cigarettes (1,31-mg estimated nicotine intake per cigarette from brands averaging 0,91 mg from machine smoking). The findings of this study are consistent with the possibility that, in the real world, compensation for nicotine is 100 % complete.[277]

Table 23 — Studies of nicotine intake compared with machine nicotine yield[[[259]]]

Study	Population	Nicotine yields (mg)	Results
Russell et al., 1980[[[278]]]	330 from smokers' clinics or research volunteers	0,5 – 3,5	PNIC versus Mach-N $r = 0,21^a$
Rickert and Robinson 1981[[[279]]]	84 during routine medical exams	0,25 – 1,3	PCOT versus Mach-N $r = 0,08$
Benowitz et al., 1983[[[280]]]	272 seeking smoking cessation therapy	< 0,1 – 1,9	BCOT versus FTC-N $r = 0,15$ ($n = 137$) $r = 0,06$ ($n = 123$)
Ebert et al., 1983[[[281]]]	76; mix of smoking cessation, hospital employees, and ambulatory patients	0,1 – 1,5	PNIC versus FTC-N $R = 0,25^a$
Gori and Lynch, 1985[[[282]]]	865 recruited from shopping malls, 10 or more cigarettes per day	0,1 – 1,6	PNIC versus FTC-N $R = 0,37^a$ PCOT versus FTC-N $r = 0,23^a$
Benowitz et al., 1986[[[283]]]	248 seeking smoking cessation (137 from previous study)	0,1 – 1,9	BCOT values similar for FTC-N 0,21 to >1,0 BCOT 2/3 of others for FTC-N < 0,20
Russell et al., 1986[[[284]]]	392 from smokers clinics	—	BCOT versus Mach-N $r = 0,13^a$ BNIC versus Mach-N $r = 0,26^a$
Rosa et al., 1992[[[285]]]	125 attending military medical center	0,38 – 1,38	BCOT versus Mach-N $r = 0,30$
Coultas et al., 1993[[[286]]]	298 from Hispanic household survey	—	SCOT versus FTC-N $r = 0,12$
Woodward and Tunstall-Pedoe, 1993[[[287]]]	2,754 from Scottish Heart Health Study (1984-1986)	0,1 – 1,7	BCOT versus Mach Tar, N, and CO and gender (multiple regression); accounted for 19 % variance
Byrd et al., 1995 [[[288]]]	33 volunteers	0,13 – 1,3	UNIC + metabolites versus FTC-N N/24 hr: $r = 0,68^*$ N/cig: $r = 0,79^*$
Hee et al., 1995 [[[289]]]	108 volunteers; 5 or more cigarettes per day	0,09 – 1,19	UNIC, UCOT versus Mach-N; NS
Byrd et al., 1998 [[[290]]]	72 volunteers	0,1 – 1,4	UNIC + metabolites versus FTC-N N/24 hr: $r = 0,19$ N/cig: $r = 0,31^a$ SCOT versus FTC-N $r = 0,15$
Jarvis et al., 2001 [[[277]]]	2,031 from 1998 Health Survey for England	0,04–1,06	SCOT versus Mach-N $r = 0,19^a$

^a $P < 0,05$

Key: PCOT = plasma cotinine concentration; BCOT = blood blood nicotine concentration; cotinine concentration; N = nicotine; concentration; Mach-N = smoking-machine-determined cotinine concentration; FTC-N = machine yield SCOT = saliva cotinine concentration; UNIC CO = carbon monoxide. nicotine yield, by Federal Trade = urine nicotine concentration; PNIC = plasma nicotine Commission method; BNIC = UCOT = urine

Based on the studies described in Table 23, it appears that cigarettes with different tar and nicotine yields as measured by the FTC method lead smokers to smoke them differently and there was a small difference in nicotine intake when high- and low-yield brands were compared. The small differences in nicotine intake between brands with high and low machine-smoked yields may be attributable to

differences in the type of smoker selfselecting to these brands, rather than to characteristics of the cigarettes themselves.

In an additional spontaneous brand switching study where smokers switched to low-yield cigarettes, the uptake of nicotine per cigarette, as measured by plasma cotinine, did not significantly change.^[291] A similar conclusion was reached by Hecht and coworkers from a cross sectional study of 175 smokers of different cigarette brands (regular to light, and ultralight) and who demonstrated no statistically significant difference in total urinary cotinine or in two biomarkers of carcinogenicity, 1-hydroxypyrene (1-HOP) and total 4-methylnitrosamino-1-(3-pyridyl)-1-butanol (NNAL). There was no correlation between tar levels, as measured by the FTC method, and any of these three biomarkers.^[292]

Therefore, the implication from these studies is that there is compensation by the cigarette smokers in order to sustain their daily nicotine intake. Compensation is achieved through adjustment of the number and volume of puffs and by vent blocking of filters.^[271] Consequently, the measurement of mainstream smoke yield of nicotine by the ISO/FTC regime underestimates the amount of nicotine intake by the smoker in general and particularly when applied to low yield cigarettes.

7.5 Nicotine yield in machine smoking methods other than FTC [e.g. Massachusetts Department of Public Health (MDPH) more intense machine-smoking parameters]

Because of the limitations of the ISO/FTC regime to inform on meaningful smoke emissions, other more intense machine-smoking regimes have been introduced. The 1999 Massachusetts Benchmark study, sponsored by the Massachusetts Department of Public Health, compiled the yields of 44 smoke constituents in the mainstream smoke; a median nicotine yield of 1,7 mg per cigarette (range 0,5 mg to 3,32 mg) was reported.^[293] It has been demonstrated that there is significant inter-individual variation in smoking topography for each brand and this has to be considered during exposure assessment. Even this more intense Massachusetts regime underestimates the amount of nicotine delivered to some smokers. In 2000, Djordjevic et al. compared smoke yields by the Massachusetts method for two leading full flavoured regular and mentholated cigarettes to those obtained by programmed method which used a pressure transducer system in an attempt to mimic puffing behaviour. This study has determined that smokers of the mentholated brand drew in 5,6 mg nicotine per cigarette and 4,1 mg for the non-mentholated nicotine yield, amounts that were twice those estimated by the Massachusetts method.^[255,256]

7.6 Nicotine yield in machine smoking methods other than FTC- Health Canada (HC) parameters

By using the even more intense settings by Health Canada for machine smoking testing, a study in 1999 of regular, light, extra-light and ultra-light varieties of leading Canadian cigarettes reported average deliveries in mainstream smoke of 2,5 mg to 2,9 mg nicotine per cigarette.^[256,294] When applied to more brands, the range was up to 3,3 mg nicotine per cigarette which obviously greatly exceeds those obtained by the ISO/FTC regime. In a 2005 study of mainstream yields of 44 smoke constituents at three smoking machine conditions (ISO, Massachusetts, and Health Canada) in a range of internationally marketed commercial cigarettes, Counts et al. have demonstrated that the yield of these constituents, including nicotine, generally increased from ISO to MDPH to HC.^[295] For the nicotine yield in mainstream smoke per cigarette, the ranges were 0,1 mg to 1,03 mg per cigarette at ISO, 0,51 mg to 2,17 mg at MDPH, and 1,07 mg to 2,7 mg at HC smoking conditions. Also the differences between absolute constituent yields among cigarettes generally decreased from ISO to MDPH to HC smoking conditions. Moreover, the rank orders of cigarettes by constituent ISO yields were generally preserved at MDPH machine smoking conditions but not HC conditions. Not surprisingly, the smoke yield changes between the smoking conditions were greater for cigarettes with higher design filter ventilation.

7.7 Summary and conclusions

Studies of subjects who smoked cigarettes with lower machine-determined yields suggest that smokers regulate their nicotine intake in order to sustain their addiction. Their smoking patterns can be affected by the design characteristics of the cigarette, and with changes in nominal nicotine delivery. Thus no single set of machine-smoking parameters will adequately reflect the wide range of individual smoking behaviours across the variety of marketplace cigarettes. Machine testing is a fixed puff protocol for

all brands whereas smoking behaviour changes systematically with the design of different brands. Experimental switching studies show varying degrees of compensation and the observed variability is related to the characteristics of the smoker and the type of cigarettes they are switched to. Spontaneous brand-switching studies suggest that there is no reduction in smoke intake per cigarette unless the smoker also cuts down the cigarette consumption. In addition, studies of smokers smoking self-selected brands show only a weak relationship between nicotine yields and nicotine exposure.

The goal of machine measure is to explore the variation in the emissions of constituents under the range of smoking conditions used by smokers; however, the currently used ISO/FTC method does not meet this objective and there is a need for development and validation of other methods that reflect common as well as the upper ranges of human cigarette smoking in order to understand the full range of delivery of these constituents, including nicotine. The purpose of an intense regime, such as 100 % vent blocking, is to define an upper range of delivery.

8 Recommendations

The recommendations for a new machine smoking regime offered in Table 24 summarize the ad hoc group's deliberations. An initial area of deliberation during the course of the discussions addressed whether any proposal for a new smoking regime should reflect available smoke uptake data or smoker yield-in-use data (i.e. smoke intake or mouth-level exposure data). It was fully recognized that mouth-level exposure data represent a measure of maximum potential smoke exposure. Smoke uptake values will be less than smoke intake values since only a portion of the smoke that is drawn out of the cigarette by the smoker is typically inhaled and retained.

While a range of views were expressed regarding the intended purpose of a new smoking regime, a consensus was developed that any proposal for a new smoking regime would be based upon guidance from mouth-level smoke exposure data.

Based upon available worldwide smoking behaviour data, three alternatives have been identified for an intense smoking machine regime. It was agreed that all three proposed regimes would produce smoke yields that were much closer to the maximum typically experienced by smokers than those produced by the current International Standard ISO 3308. As such, any one of the proposed regimes is potentially suitable as a new practical machine smoking regime for use in addition to the existing ISO standard (ISO 3308). However, there was no consensus on any one of the alternatives — each has its strengths and limitations and these are briefly summarized below.

Taking into account both the reviews of human behaviour data and smoking machine capabilities, a 30 s puff frequency is appropriate for a proposed new smoking regime. A puff duration of 2 s and the butt length parameters specified by the current ISO standard are also appropriate for a proposed new smoking regime. The group acknowledged the interaction between the various smoking behaviour parameters such that a change in one parameter could directly influence other parameters. This was especially evident when the relationships between vent blocking and puff volume are examined. The various regimes offered below attempt to account for this relationship.

Table 24 — Three alternatives for an Intense Smoking Machine Regime based on human smoking behaviour data

Option	Puff volume (ml)	Puff frequency (s)	Puff duration (s)	Vent blocking (%)	Principal rationale
A	55	30	2	50	<p>1 Based on the upper range of observed smoker vent-blocking behaviour.</p> <p>2 Based on the upper range of smoker puff volume behaviours for most cigarettes sold (5 mg ISO “tar” yield and above) when 50 % vent blocking is considered.</p> <p>3 Puff volume slightly lower than 90th percentile for 1 mg ISO “tar” products, based on available data.</p> <p>4 Actual yields observed for some individual smokers of 1 mg ISO “tar” yield cigarettes (~ 15 % to 20 %) may exceed machine-generated yields based on these parameters. For other cigarettes, expected to produce machine yields greater than actual average yields experienced by most smokers.</p>
B	60	30	2	50	<p>1 Puff volume based on 90th percentile for 1 mg ISO “tar” yield cigarettes, when 50 % vent blocking is considered.</p> <p>2 Expected to produce machine yields even greater than actual average yields experienced by many smokers of higher ISO “tar” yield cigarettes (most cigarettes sold).</p> <p>3 Puffing parameters may not be achievable with smoking machines used for large scale biological testing (in vivo studies).</p>
C	45	30	2	100	<p>1 Exceeds the upper range of observed smoker vent blocking behaviour.</p> <p>2 Based on the upper range of smoker puff volume behaviours when 100 % vent blocking is considered.</p> <p>3 Expected to produce machine yields greater than actual average yields experienced by most smokers.</p> <p>4 Limits the relative difference between smoke yields of different cigarettes to the greatest extent (~ flat yield curve).</p> <p>5 Greatest variability in observed results expected.</p>
NOTE Current ISO method butt length standard applies in each case.					

8.1 Option A

The 50 % vent blocking in this proposed regime was based on published data indicating that maximum and deliberate vent blocking by either smokers’ lips or fingers results in at most 50 % of the cigarette filter ventilation holes being blocked. The upper range of observed smoker vent blocking behaviour and the puff volume (55 ml) was at the upper range of puff volume for most cigarettes sold — that is for cigarettes that deliver 5 mg or more of tar (as judged by the current ISO or FTC standards). However, based on the limited data available for cigarettes that deliver 1 mg tar (ISO/FTC), the puff volume is below the 90th percentile of smokers who use these very low tar delivery cigarettes. An examination of human yield

data obtained from US filter studies, see reference,^[296] indicates that around 15 % to 20 % of smokers of 1 mg tar yield US cigarettes obtained yields in excess of those produced by the Massachusetts smoking regime. Although Option A has a larger puff volume (55 ml) than the Massachusetts smoking regime, the group formed the view that some smokers of 1 mg tar yield cigarettes would still exceed the yields produced by the proposed regime. On the other hand, the group believed that the proposed regime will produce higher yields than actually experienced by most smokers of products with ISO yields greater than 5 mg (the vast majority of cigarettes sold in the world today).

8.2 Option B

In this regime, the puff volume is increased to 60 ml but otherwise the parameters are identical to those of Option A. The puff volume in this regime represents the upper range of puff volume observed in smokers of 1 mg ISO/FTC tar yield cigarettes. It is expected that this regime will produce machine yields higher than those of Option A for all cigarettes, particularly those that have higher ISO/FTC tar yields than 1 mg — most cigarettes smoked.

From a practical standpoint, increasing the puff volume to 60 ml may require a modification of some older style smoking machines to fit syringes capable of producing the required puff volume. Both options A and B require the blocking of 50 % of the ventilation holes. This is based on experimental data indicating that maximum and deliberate vent blocking with lips and fingers results in at most 50 % of the ventilation holes being blocked. However, manually blocking 50 % of the ventilation holes **accurately** with tape is a difficult procedure to perform and may be impracticable if a large number of cigarettes are to be smoked. If this option is adopted, it may require the development of a new style holder that will incorporate a 50 % ventilation block and will be suitable for use with cigarettes differing in filter lengths, circumferences and positions of ventilation.

8.3 Option C

In this option, the vent blocking (100 %) exceeds the degree of blockage reported from studies aimed at determining the degree of blockage when smokers deliberately and maximally block with lips or fingers. The 45 ml puff volume is based on the upper range of smoker puff volumes observed in experimental conditions where 100 % vent blocking is imposed. This regime is likely to produce machine yields greater than actual average yields experienced by most smokers, irrespective of the type of cigarette smoked. One practical advantage of this option is that a 100 % vent block with tape is far easier to achieve than an accurate 50 % vent block.

8.4 Variability and reproducibility of data

All of the options (A, B and C) will diminish the relative difference between smoke yields of different cigarettes. Option C will do this more than Option A or B. In addition, studies comparing the repeatability, see reference,^[297] (measurement variability within a laboratory) and reproducibility, see reference,^[298] (measurement variability from different laboratories) of yield data obtained from the ISO/FTC, Massachusetts (50 % vent block) and Canadian intense (100 % vent block) regimes indicates that the three proposed options are likely to result in poorer precision (i.e. greater absolute measurement variability) than the current ISO/FTC regimes. For reasons that are not entirely clear, option C (100 % vent block) is likely to produce the most variable tar, nicotine and carbon monoxide results, with the largest degree of variability expected for carbon monoxide measurements. The current ISO standard (ISO 4387) requires reporting average tar (i.e. NFDPM) yields per cigarette “to the nearest 1 mg.” Given the increase in measurement variability expected with a more intense smoking regime, such a requirement should be carefully considered when developing any new reporting guidelines associated with a more intense smoking method.

8.5 Gaps in knowledge

There was a general recognition within the group that no single machine regime could model human smoking behaviour. All of the data reviewed indicated a) large differences between the puff parameters of individuals smoking the same type of cigarettes, b) changes in puff parameters that occurred within

individuals as they smoked single cigarettes and c) smokers may vary their puff parameters when smoking the same cigarette type on different occasions.

There is a paucity of data from countries outside North America and Europe. Some of the studies emanated from smokers in Brazil, Australia and New Zealand, but the vast majority of the data were from studies in Europe and North America. This was recognized as a particularly important deficit because of the large smoking population in developing countries.

There was very little data available on smoking topography of smokers using very low yield cigarettes (1 mg to 3 mg tar, ISO). Similarly, there were very few smoke uptake studies with smokers smoking these cigarettes. Although the dearth of data are indicative of the very few people (<5 % of smokers) who use these products, it was felt that more data from this group of smokers would perhaps better inform the recommendation of a new smoking standard.

The general relationship(s) between smoke intake (mouth level exposure) and smoke uptake (the fraction of smoke retained by the smoker) have not been widely established for individual smoke components, widely diverse smoking populations and cigarettes from different geographical regions. As such, for a range of cigarettes with different ISO tar yields, the slope of smoke (tar or nicotine) yield curves resulting from a new method may not be identical to the slope of smoke (nicotine) uptake curves observed in population-based studies.

Finally, there are no data on the machine yields of any of the options presented. The recommendations and deliberations were guided by extant data and interpretations of how the various parameters interact in smokers.

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