



67th Tobacco Science Research Conference
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Do Cigarette Smoke Yields from a Single Smoking Regime Fit with Current Regulatory Objectives?

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Content

- 1 Regulatory purposes & proposals for 2 smoking regimes
- 2 Issues faced with an intense smoking regime
- 3 Cigarette burning under different smoking regimes
- 4 Another possible way to fit to regulatory purposes?
- 5 Conclusions

Regulatory Purposes and Proposals

CANADA

- **2000; Tobacco Products Information Regulations adopted**
 - Requirement for testing, reporting and labeling of emissions measured with two smoking regimes which would **inform the consumer and the regulator of the ranges of emissions**
- **Sept, 2011; Regulations Amended**
 - *“...**the numerical values for toxic emissions** that currently appear on tobacco product packaging **have been found to be confusing and not clearly understood by smokers.**”*

WHO

- **April 2007 - A/FCTC/COP/2/8 about Art. 9 on Product regulation**
 - Item 10: *“...**the main objective of testing and measuring tobacco product ...would be for the purposes ... to characterize and monitor cigarettes**”*
- **August 2008 - A/FCTC/COP/3/6**
 - *“**All machine-smoking regimens have limitations; none can generally represent human smoking patterns, exposure or risk.**”*
 - *“... methods to test and measure emissions should provide for machine smoking of cigarettes to **help characterize the smoke and to monitor any change over time.**”*

To date, Canada and WHO still require or recommend two smoking regimes

Regulatory Purposes and Proposals

USA

- **June 2009 - USA: Family Smoking Prevention and Tobacco Control Act**
 - Section 904
 - Each tobacco product manufacturer shall submit **a listing of all smoke constituents** identified as **harmful or potentially harmful (HPHC)**
 - Not later than 3 years after the date of enactment, the Secretary shall **publish** in a format that is **understandable and not misleading to a lay person**
 - Section 915
 - The regulations shall require testing and reporting of tobacco product smoke constituents that the Secretary determines should be tested **to protect the public health**
- **March 2012-FDA Proposal - Draft Guidance**
 - The quantity of each HPHC in cigarette smoke should be **determined by both the non-intense and intense smoking regimes**
 - The two smoking regimes are expected to provide **information about different deliveries of HPHCs** possible for each tobacco product

Regulatory Purposes and Proposals

Consensus on:

No machine smoking regime provides a valid estimate of exposure

No consensus on:

What is understandable and not misleading information

Not demonstrated:

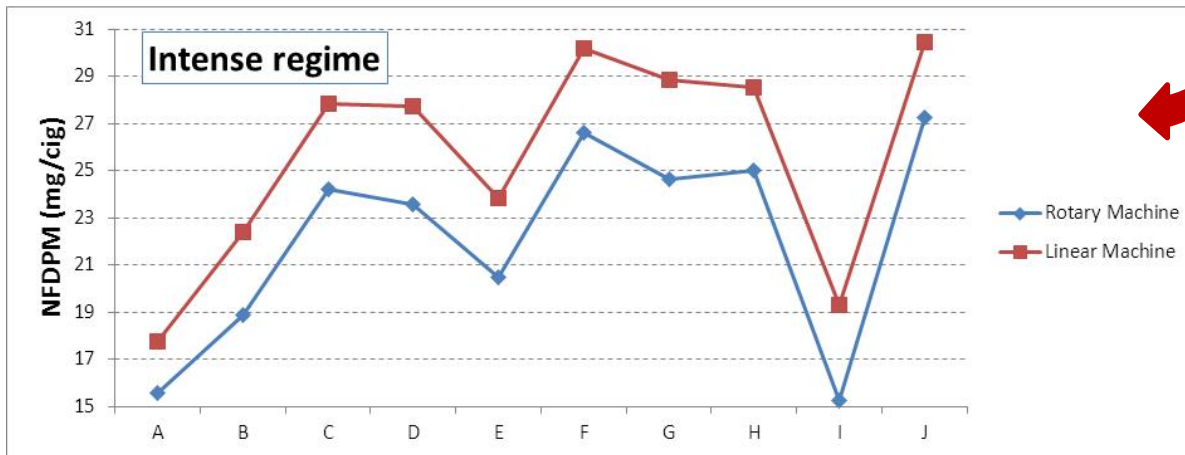
That two smoking regimes would lead to an improved characterisation of the emissions, and a better product monitoring

Issues with intense smoking regime

Puff vol: 35ml
Puff freq.: 60s
Filt. Vent.: Open



Puff vol: 55ml
Puff freq.: 30s
Filt. Vent.: Blocked



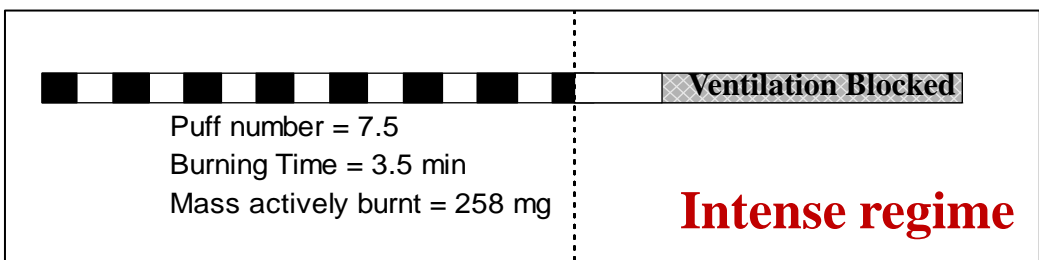
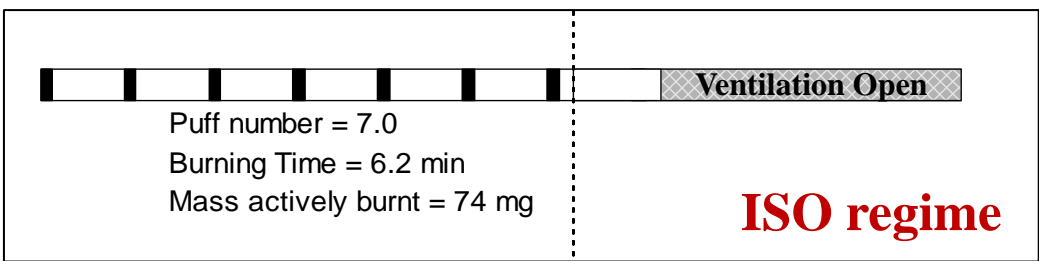
Increase
of the
Reproducibility

Investigations of ISO/WG10 suggest phenomenon of condensation/desorption

Cigarette burning model

A descriptive model based on simple hypotheses (2012):

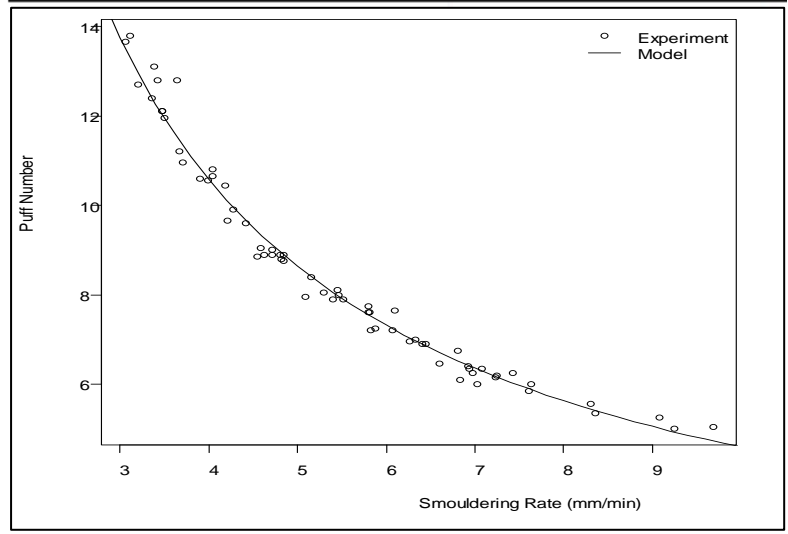
- Constant mean burning rate between puffs
- Length burnt during a puff proportional to puff volume and smouldering rate
- Linear increase of coal airflow as the tobacco rod burns



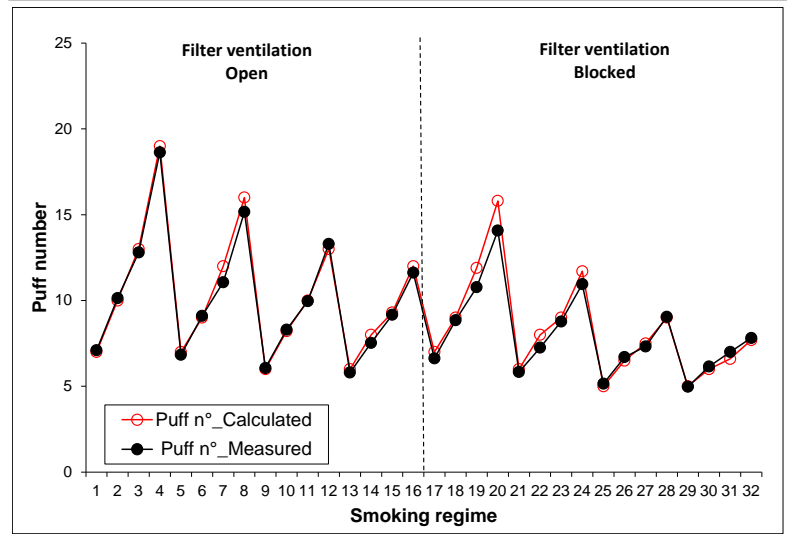
And able to predict:

- Puff number
- Weight of tobacco actively burnt
- Smoking time

Test with several burning rates

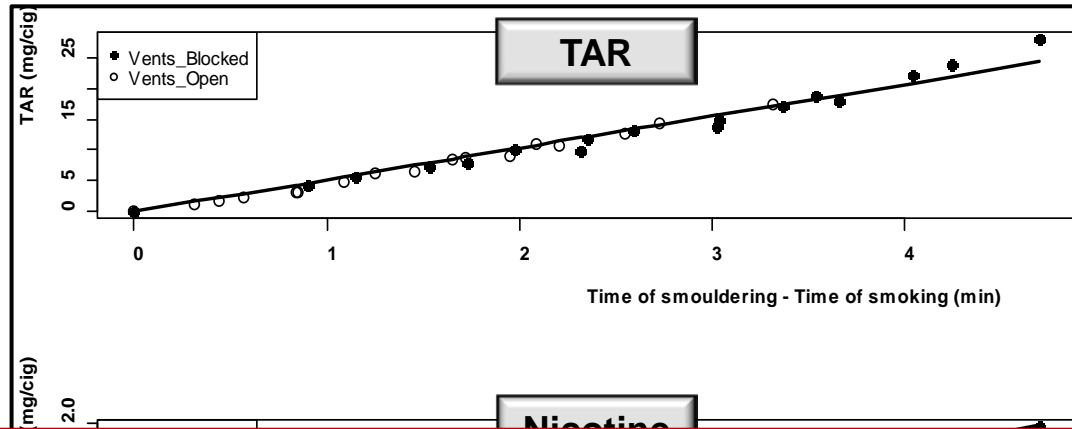


Test with several smoking regimes

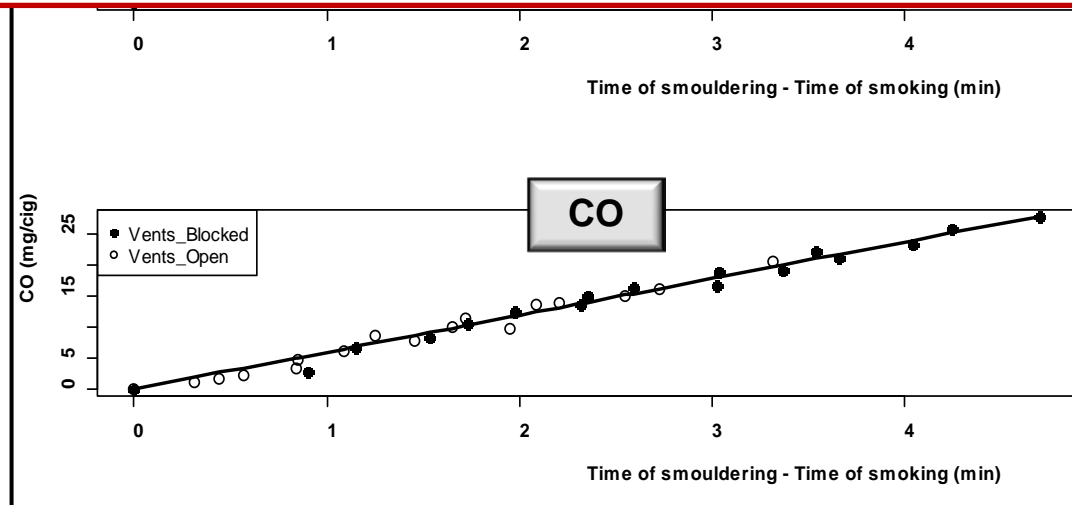


Cigarette burning model

KS format
Diameter: 7,8mm
Filt. Vent.: 52%
Non LIP compliant

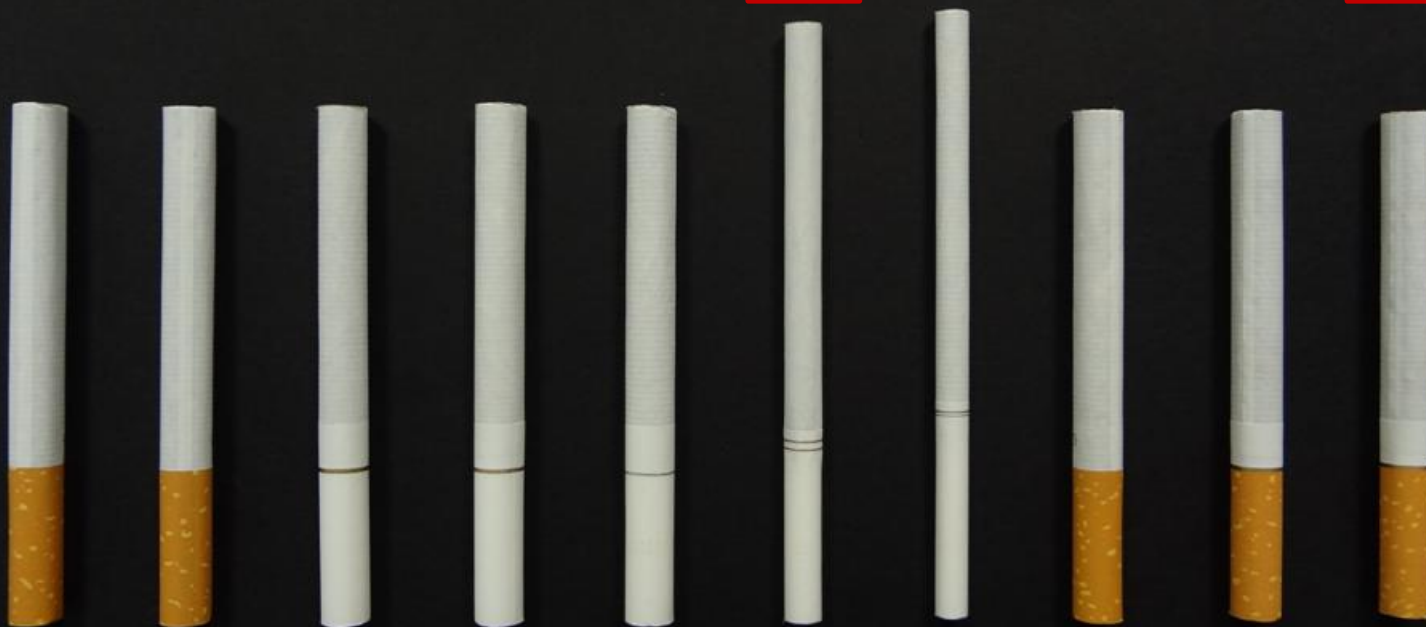


Is it still valid with other product designs?



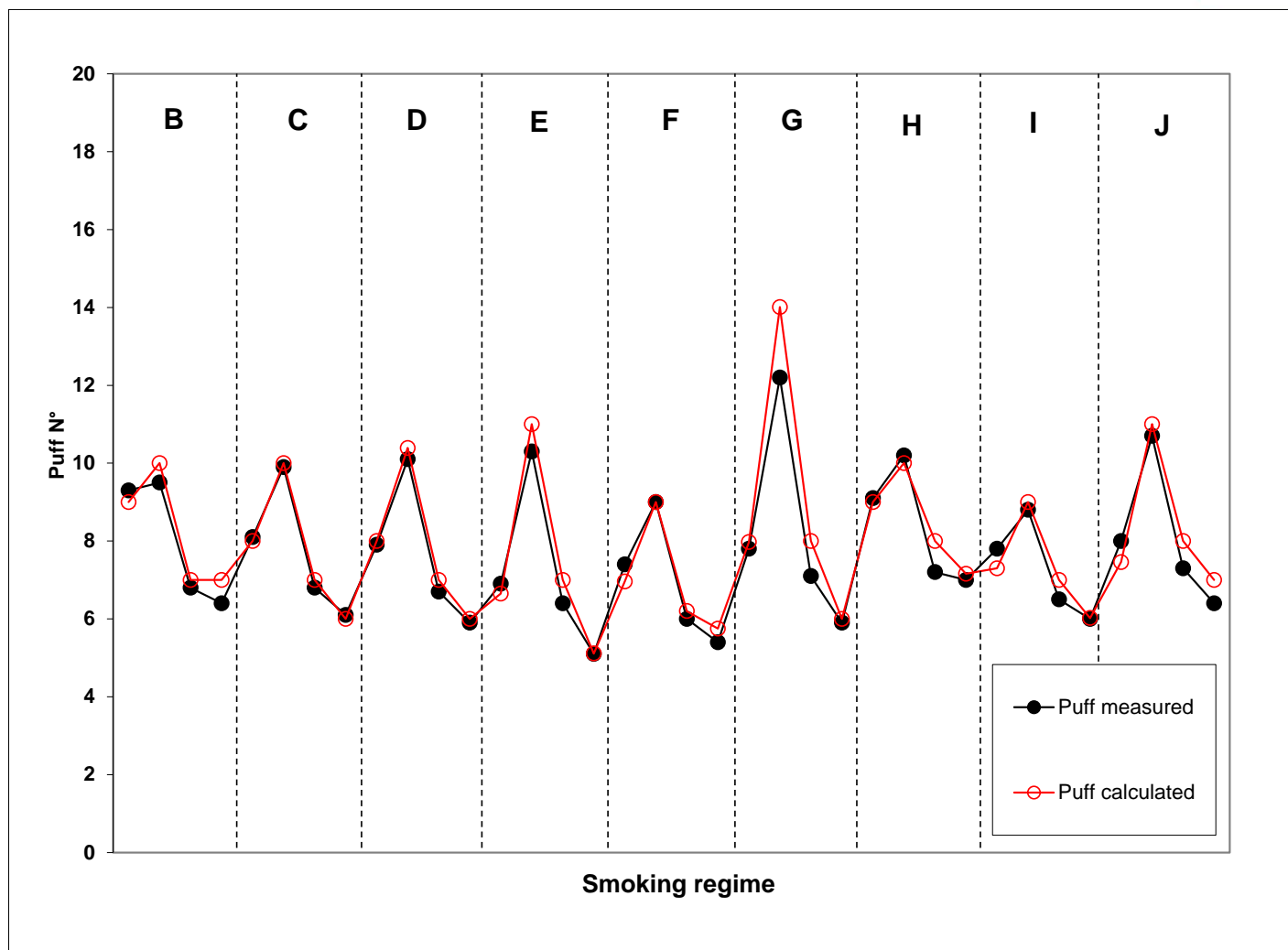
Samples tested & smoking regimes

Product	A	B	C	D	E	F	G	H	I	J
LIP compliant	No	No	No	No	No	No	No	Yes	Yes	Yes
Diameter (mm)	7.8	7.8	7.8	7.8	7.8	6.1	5.4	7.8	7.8	7.9
Filter ventilation (%)	52	14	40	50	72	47	87	19	32	52
Length (mm)	83	83	83	83	83	97	99	83	83	83
Smould. rate (mm/min)	6.8	6.6	6.1	6.7	7.1	8.8	8.1	5.5	5.6	5.0



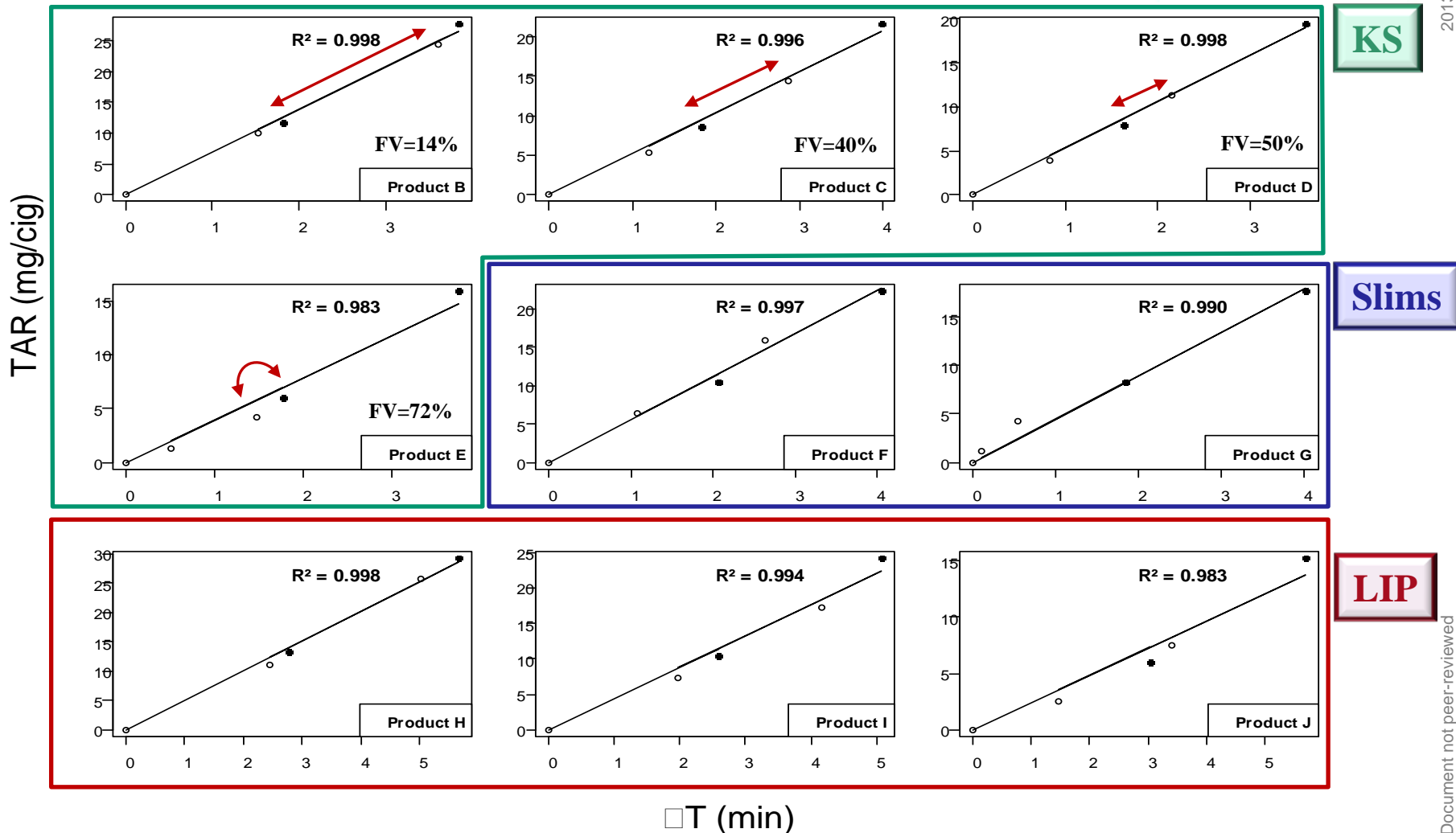
Product	A	B	C	D	E	F	G	H	I	J
Puff volume (ml)	17.5/35/55/70					35/55				
Puff interval (s)	20/30/40/60					30/60				
Filter ventilation	Open/Blocked					Open/Blocked				
N° of regimes	32					4				

Puff number measured/calculated



Good agreement for all the products

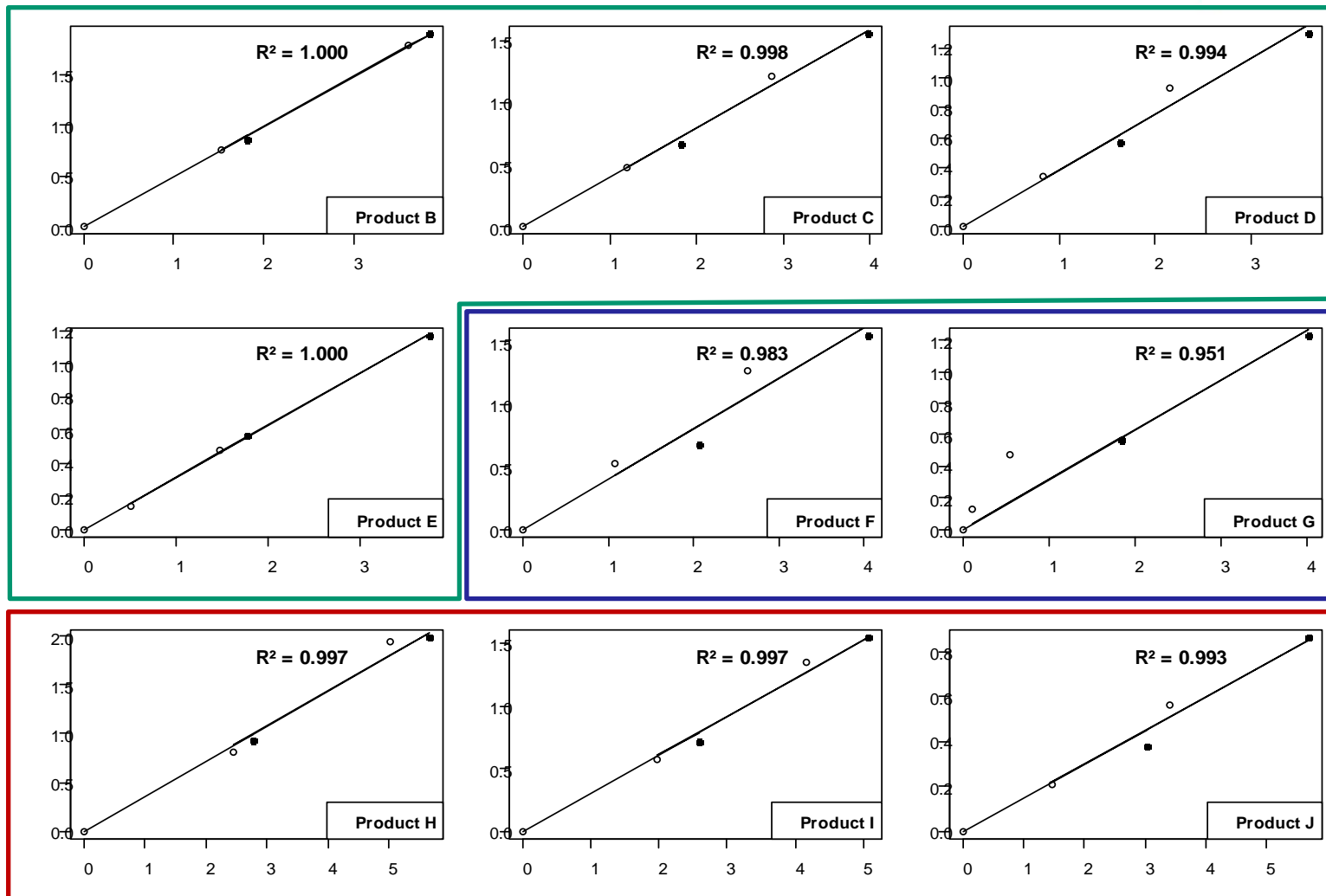
TAR versus ΔT (Smoulder - Smoking Time)



The model also applies for LIP products for which there is an average effect of the burn rate due to the random positioning of the bands

Nicotine versus ΔT (Smoulder - Smoking Time)

Nicotine (mg/cig)



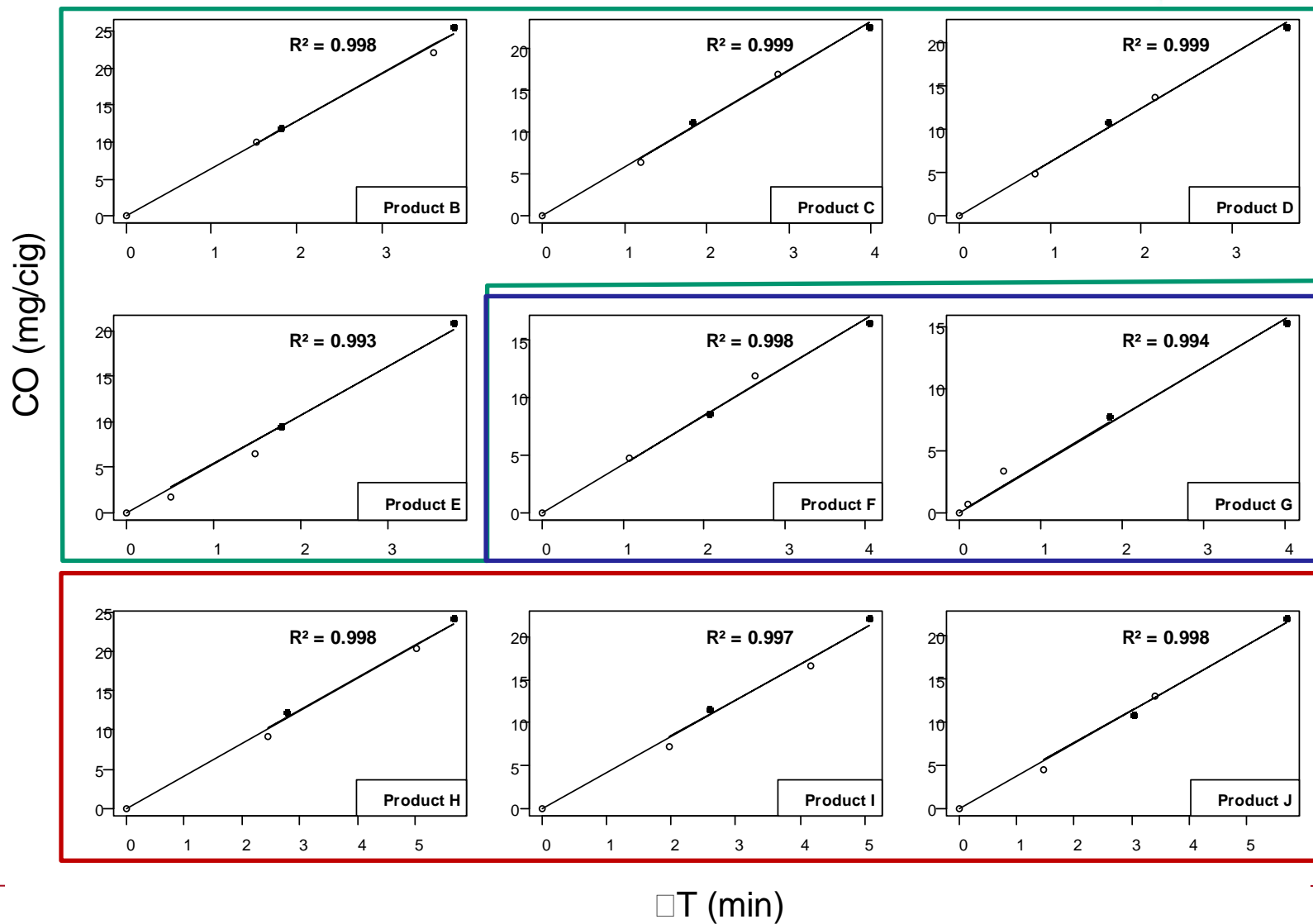
KS

Slims

LIP

ΔT (min)

CO versus ΔT (Smoulder - Smoking Time)



KS

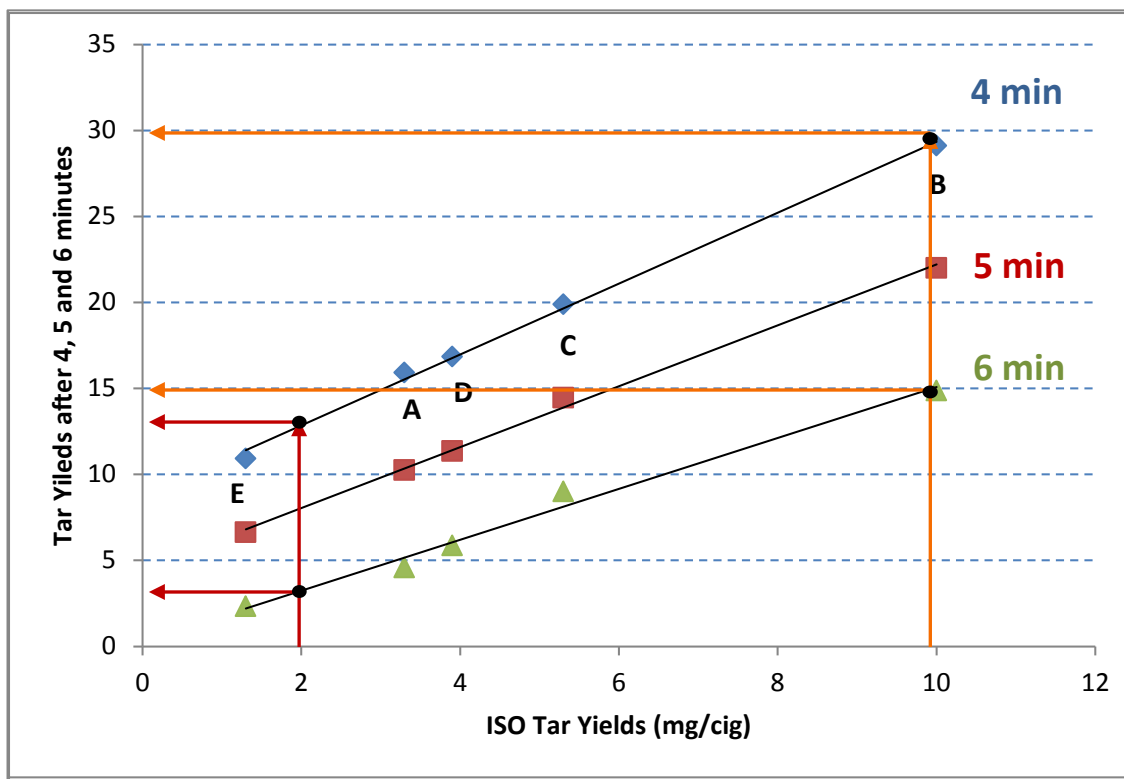
Slims

LIP

Another Way to Fit to Regulatory Objectives?

- **Objective of product characterisation**
 - A single smoking regime appears to be sufficient for characterizing a product for TNCO yields and smoking intensity. There is no evidence that a second regime would add value since yields are simply related to burning time.
- **Objective of product monitoring**
 - The association of ISO yields with an appropriate set of physical parameters could fit to the regulatory objective.
- **Objective of communicating understandable, not misleading information**
 - The association of ISO yields with a corresponding burning time would provide such information with the benefit to link yields and behaviour (time).
 - The relationship TNCO yields-burning time is valid with filter ventilation open or blocked and the burning time is easily derived from the puff number.

Another Way to Fit to Regulatory Objectives? Illustration – Products KS / A to E



For a given smoking time, the yield ranking follows that of ISO

Possible alternative

Which optimal sets of data to fit to the Regulatory Purposes?

WHAT	WHY
ISO smoking regime yields	<p>One smoking regime characterizes the products (yields vs smoking intensity)</p> <p>The ISO regime is more robust than the intense regime (cf ISO/WG10)</p> <p>Any mandate of lowering toxicant is possible with the ISO regime (cf CO)</p> <p>The intense regime is not less misleading (cf Canada)</p>
Filter Ventilation	<p>This is a key design parameter and then useful for product monitoring</p>
Puff number	<p>This is measured during the smoking (no extra testing burden)</p> <p>This is correlated to smouldering rate for given cigarette dimensions</p> <p>A burning time can be estimated and associated with the yields</p>
Cigarette dimensions	<p>This complements the information on puff number</p>

Conclusions

- ① The main regulatory purposes are:
 - Protection of the public health
 - Product characterisation and monitoring
 - Information to the public
- ② It is not clearly understood how an additional smoking regime could better support these purposes, especially when this regime is not robust
- ③ Due to the linear relationship between yields and burning time, a single smoking regime associated with a number of relevant parameters could fit to the regulatory purposes
- ④ The association of the smoking time to yields provides the missing dimension making the information about deliveries understandable and not misleading

Perspectives

- ① Is it still valid with other smoke constituents?
- ② Can we confirm the link between burning time and human smoking yield?



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