



SCIENTIFIC AND REGULATORY CHALLENGES FOR MACHINE MADE CIGARS

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AGENDA

1. 50 years of scientific backlog
2. Differences in regulation – cigarettes and machine made cigars
3. Differences in products characteristics
4. Typical variability of machine made cigars
5. The challenges related to variability
6. My hope for a regulatory approach



50+ YEARS OF SCIENTIFIC BACKLOG

An overwhelming body of research has been carried out on cigarettes and cigarette tobacco over the last 50+ years.

Agronomy, leaf chemistry, tobacco processing, cigarette design, additives, pyrolysis studies, smoke constituents, smoking behaviour and health effects.

Only a small fraction of this has been done for machine made cigars or cigar tobacco.

From a science point of view we know a lot less about machine made cigars.



50+ YEARS OF SCIENTIFIC BACKLOG

Illustrated by the number of publications

Search terms	Google Scholar		CORESTA Abstracts		Medline	
Cigarette + tobacco	1180000	6.9 %				
Cigar + tobacco	82000					
Cigarettes			3087	5.2%		
Cigars			160			
Flue cured			1242	4.0 %		
Dark air cured			50			
Cigarette smoking					12872	0.44 %
Cigar smoking					56	



DIFFERENCES IN REGULATION

Cigarettes have been subject to requirements about testing, reporting and/or disclosing smoke yields for more than 50 years.

Some parts of the world have had tar, nic. and CO ceilings.

Cigarettes are a very homogeneous product category, with high volume relatively few brands and variants. Deep understanding of what drives the smoke yields.

For machine made cigars there has not been the same push to understand what drives smoke yields. The much smaller product category has diversified into a very wide variety of shapes and sizes.

Cigarettes	Machine made cigars
Homogenous	Inhomogenous
High volume per SKU	Low volume per SKU
Well understood	Not understood



<3lb



>3lb



>4lb



Plastic Tip



Wood Tip



"irregular shape"



Large



DIFFERENCES IN PRODUCT CHARACTERISTICS

Cigarettes are characterized by:

- Tobacco blends produced in large volumes where differences from farm to farm are smoothed out through extensive blending.
- Standardized seeds.
- A highly controllable paper wrapper.

Cigars are characterized by:

- Few tobacco grades in low volume from few farmers, in few countries, where farmers produce their own seeds.
- A variable (HTL) or highly variable (natural) wrapper.
- A variable (HTL) or highly variable (natural) binder.
- Often a threshed (rather than cut) filler
- Leaf is matured/fermented in multiple different ways.

All of these parameters results in much higher variability in physical as well as chemical parameters.

Typical variability of cigar tobacco



Comparison of same leaf grades* from different crop years

	Ammonia	As	Cd	Nic	NNN	NNK
	% (DWB)	ug/g (DWB)	ug/g (DWB)	mg/g (DWB)	ug/g (DWB)	ug/g (DWB)
Dark air cured type1 2013 (rep 1)	0,584	0,078	1,23	10,70	17,20	5,66
Dark air cured type1 2013 (rep 2)	0,654	0,076	1,24	12,40	18,00	5,58
Dark air cured type1 2013 AVG	0,619	0,077	1,23	11,60	17,60	5,62
Dark air cured type 1 2014 (rep 1)	1,080	0,144	1,77	21,90	12,00	2,16
Dark air cured type 1 2014 (rep 2)	1,060	0,128	1,87	22,00	11,80	2,06
Dark air cured type1 2014 AVG	1,070	0,136	1,82	21,90	11,90	2,11
Diff between averages	73%	77%	48%	89%	32%	62%

	Ammonia	As	Cd	Nic	NNN	NNK
	% (DWB)	ug/g (DWB)	ug/g (DWB)	mg/g (DWB)	ug/g (DWB)	ug/g (DWB)
Dark air cured type2 2014 (rep 1)	1,007	0,101	2,79	19,10	19,90	2,96
Dark air cured type2 2014 (rep 2)	1,001	0,100	2,78	16,30	19,90	2,97
Dark air cured type2 2014 AVG	1,004	0,100	2,79	17,70	19,90	2,97

Dark air cured type2 2015 (rep 1)	0,686	0,133	1,39	18,30	12,30	3,08
Dark air cured type2 2015 (rep 2)	0,612	0,125	1,51	17,80	12,40	3,04
Dark air cured type2 2015 AVG	0,649	0,129	1,45	18,00	12,40	3,06
Diff between averages	35%	29%	48%	2%	38%	3%

* Same: seed, country, area, farmer, texture, colour

Typical variability of cigar tobacco



Comparison of same leaf grades* from different farms

	Ammonia	As	Cd	Nic	NNN	NNK
	% (DWB)	ug/g (DWB)	ug/g (DWB)	mg/g (DWB)	ug/g (DWB)	ug/g (DWB)
Dark air cured type3 2015 (rep 1) Farmer A	0,809	0,029	2,44	32,10	22,8	4,37
Dark air cured type3 2015 (rep 2) Farmer A	0,833	BQL	2,45	32,10	22,7	4,1
Dar air cured type3 2015 AVG Farmer A	0,821	0,029	2,44	32,10	22,7	4,24
Dark air cured type3 2015 (rep 1) Farmer B	0,400	0,145	2,64	33,20	46,20	3,08
Dark air cured type3 2015 (rep 2) Farmer B	0,372	0,134	2,84	23,70	51,50	2,75
Dark air cured type3 2015 AVG Farmer B	0,386	0,139	2,74	28,50	48,80	2,91
Difference between averages	53%	379%	12%	11%	115%	31%

Very significant natural variability in the leaf

* Same: seed, country, area, texture, colour, crop year

Variability of cigar smoke data



Cigar Smoking Method Sub-Group: Technical Report on 12th Collaborative Study – January 2018

Nicotine [mg/cigar]						
Sample	Nb of labs	Mean	r	R	CVr	CVR
B	7	1.038	0.2018	0.3212	19.4%	31.0%
C	7	3.379	0.4927	1.1705	14.6 %	34.6%
E	5	1.981	0.9193	1.1799	46.4%	86.6%
G	7	1.386	0.1857	0.4982	13.4 %	35.9%

NFDPM [mg/cigar]						
Sample	Nb of labs	Mean	r	R	CVr	CVR
B	7	19.43	2.868	4.496	14.8%	23.1%
C	7	45.01	6.213	10.128	13.8%	22.5%
E	5	102.02	27.58	47.925	27.0%	47.0%
G	7	12.55	2.466	3.120	19.6%	24.9%



SUMMARY OF DIFFERENCES BETWEEN CIGARS AND CIGARETTES

Due to the regulatory history as well as the industry structure and the inherent product characteristics, cigars are significantly more variable than cigarettes.

Test methods for machine made cigars are still in the progress of being developed and improved.

The industry is only beginning to document this variability. Very little data exists. The understanding of what drives the variability is very limited.

What are the challenges related to this?



THE CHALLENGE RELATED TO VARIABILITY

- Isolated test results – without the knowledge of the medium to long term variation is of little use.
- Not knowing what drives variation makes it difficult/impossible to control the outcome.
- Regulation not taking the variability into account is a significant challenge for manufactures.

Example

The cigarette industry is required to report the concentration of certain constituents and subsequently are de facto expected not exceed these, e.g. in connection with blend maintenance or substantial equivalence applications.

Similar requirements for machine made cigars would be extremely challenging.



THE CHALLENGE RELATED TO VARIABILITY

- The predictive models for basic smoke yields (Tar/Nic/CO) in machine made cigars are rudimentary or non-existent. The results are characterized by significant variation within and between lab as well as from batch to batch.
- If the industry is required to test and report multiple constituents in smoke, without knowing what drives the variation in Tar/nic/CO, that would only create useless data.
- Manufactures of machine made cigars are in the process of documenting this variability, but small volumes (compared to cigarettes) and a large number of brand variants constitute a significant challenge.



MY HOPE FOR A REGULATORY APPROACH

- Regulators and industry work together with the aim to build up a basic understanding of the machine made cigar category including the natural variability of leaf characteristics and the effects on tar, nicotine and CO deliveries.
- Development and improvement of relevant test methods need to be in focus.
- Recognise that the starting point for our knowledge is way behind the status of cigarettes.
- Future regulation for machine made cigars should be based on the analysis of robust data to fill these current knowledge gaps.



THANK YOU

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