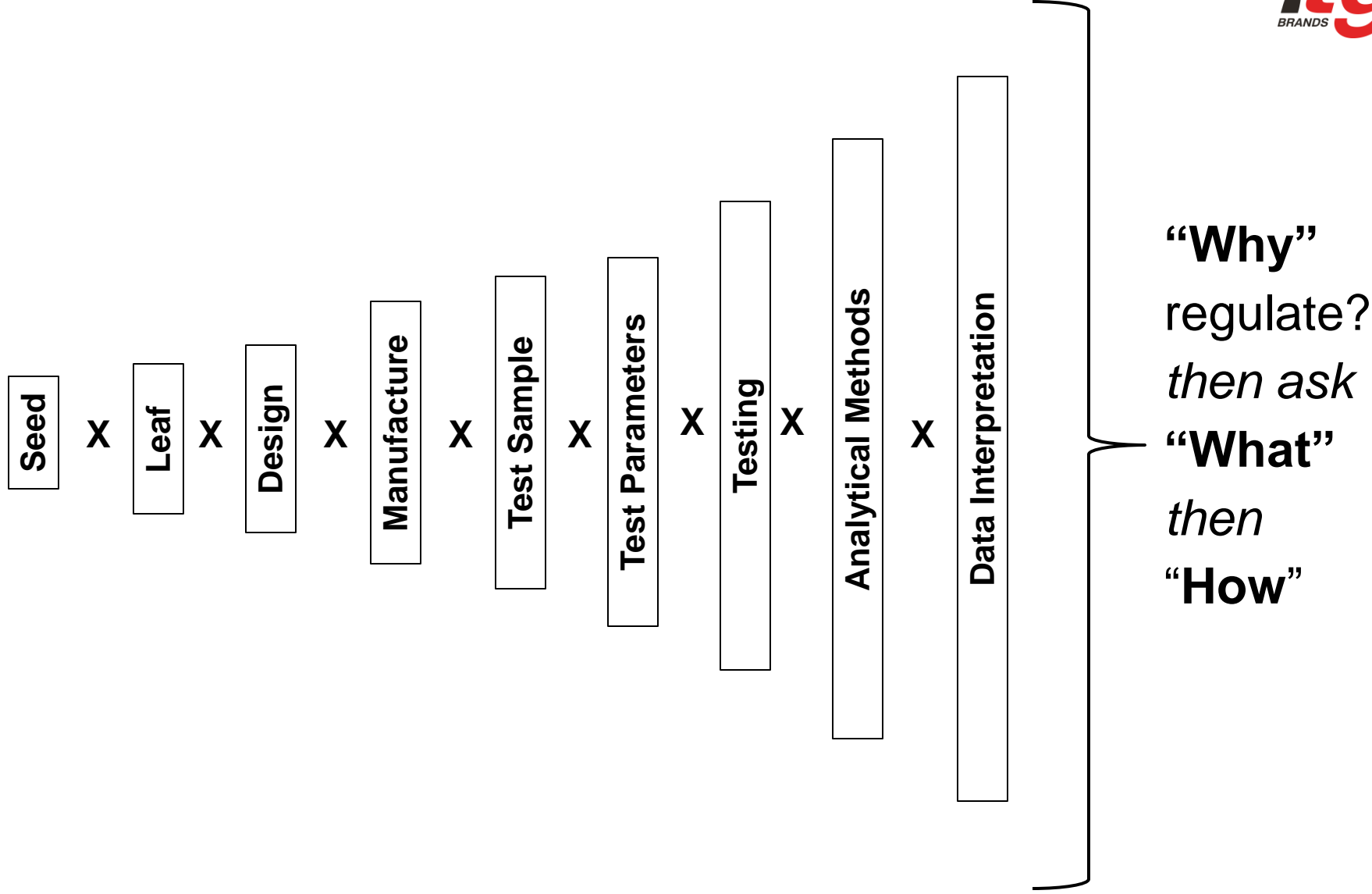
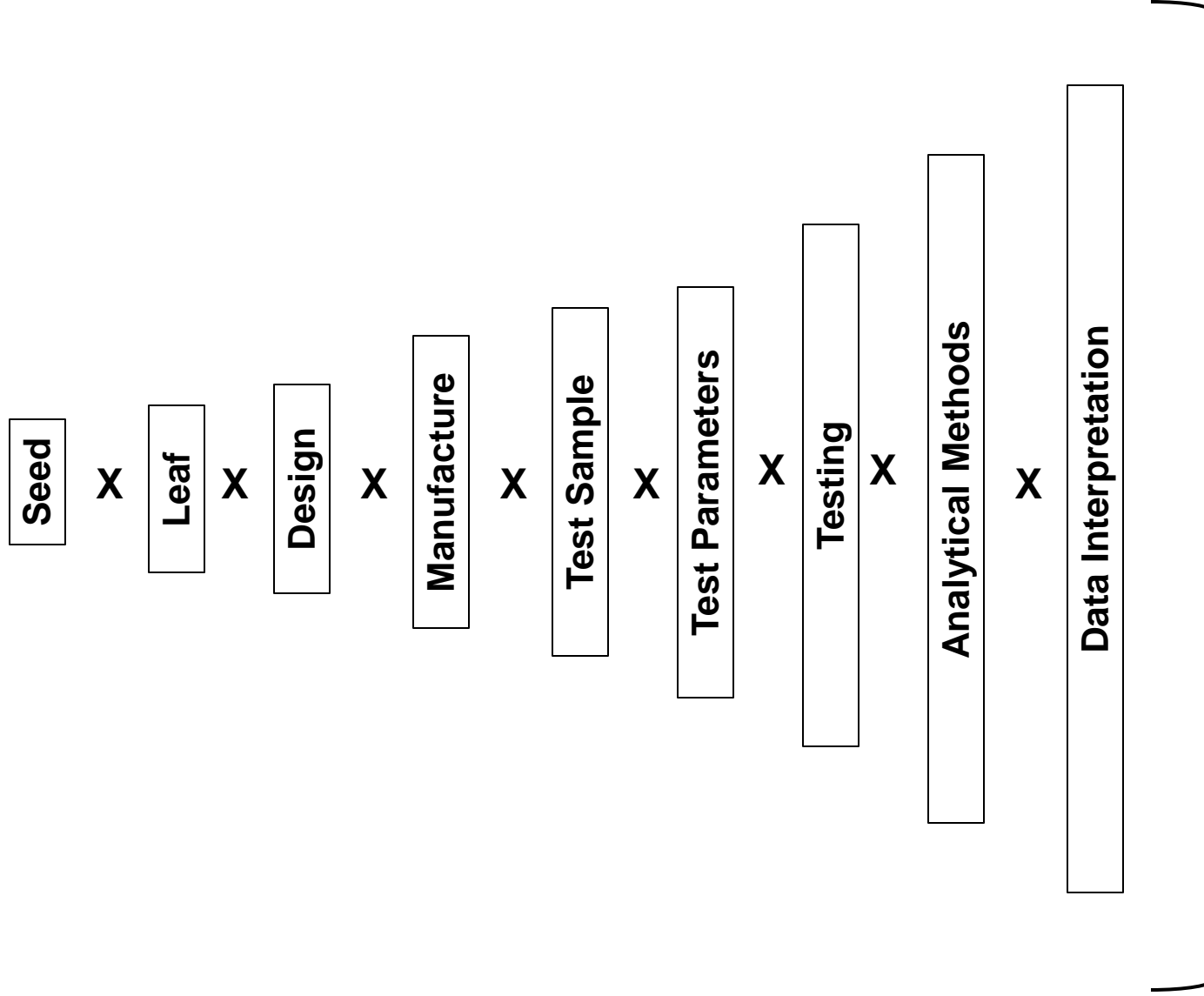


CIGARS: COMPOUNDING VARIABILITY



CIGARS: COMPOUNDING VARIABILITY



“Why”
regulate?
then ask
“What”
then
“How”

BUILDING BLOCKS FOR REGULATED TOBACCO PRODUCTS AND THE CHALLENGES WITH CIGARS “*STRIKING THE RIGHT BALANCE*”

Katherine Ciabrone

SVP, Product Integrity & Compliance,
Chief Compliance Officer

AGENDA



- Current Cigar Regulation
- Risk-based approach to regulatory frameworks
- Controls relative to Cigar risks
- Summary

GLOBAL CIGAR REGULATION



- Cigars typically represent a small part of a countries tobacco market and have been a lesser focus for regulatory action than cigarettes
- Of countries who currently regulate cigars, focus is mostly on physical measurements, ingredients and marketing information

Who	What
EU	Various combinations of Launch & Changes, Pre-notification, Product Weight , Tobacco Cure method (Air), Ingredient Weight & CAS (eg Glues), Package Type, Pack Units, Cigar Dimensions (mm)
Canada	Product Weight, Tobacco type (Dark Air Cured), Ingredient Weights & CAS (ex Glues), % Pack Moisture, Packaging parts, Cost of Packaging Materials, Manufacturing Procedures, Sales volumes, Quarterly, looking ahead at Country of origin, Biological origin, Brand name consistent across all evidence
Bahrain	Ingredients, Paste details & weight and launch details
Saudi Arabia	
UAE	
Norway	
Switzerland	
Israel	
Russia	
Ukraine	
Taiwan	

GLOBAL CIGAR REGULATION



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Who	What
EU	<p style="text-align: center;">Product Quality</p> <p style="text-align: center;">Mainly focused on adulteration, contamination and mislabeling</p>
Canada	
Bahrain	
Saudi Arabia	
UAE	
Norway	
Switzerland	
Israel	
Russia	
Ukraine	
Taiwan	Ingredients, Paste details & weight and launch details

GLOBAL CIGAR REGULATION – ADDITIONAL REQUIREMENTS



Canada: Characterizing Flavors

- There is a restriction on Characterizing Flavors. Defined as “*has a clearly noticeable smell or taste other than tobacco), is packaged or labeled as being flavored, or is listed under the regulations as a flavored tobacco product*”
 - **6. What are some examples of flavours that cannot be sold in Alberta after June 1, 2015?**
 - Examples of characterizing flavours that will be banned include, but are not limited to: fruit, chocolate, honey, spice, clove, herb, alcohol, candy, and vanilla.

Brazil: Analytical Testing (Leaf, not Smoke)

- Certificate of analysis for each product that had been issued within the 6 months before market launch.
- Ammonium, Nicotine, Nor nicotine, Myosmine, Anabasine, Antabine, NNN, NAT, NAB, NNK, Pb, Cd, Hg, Ni, Se, Cr, As, Eugenol, pH, Benzo(a)pyrene, Glycerol, Propylen glycol, Triethylene glycol, Nitrate, Triacetine, Sodium propionate, Sorbic acid, Menthol

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**Public Health
Consumer Use and
Behaviour**

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USA: CIGAR MARKET UNDER DEEMING REGULATIONS



- **US FDA Center for Tobacco Products began to regulate cigars like cigarettes in August 2016.**
- **Current requirements:** Health Reports, Product and Ingredient Listings, Contamination & Adulteration, new Package Warnings
 - **No new Cigars** without regulatory pre-market approval
 - *Almost any change in product design, ingredients results in being a 'new product'*
- **2021 Cigar Regulatory Submission**, including Design Parameters, Ingredients, Materials, **Leaf and Smoke HPHCs (possibly HPHC 20)**, Packaging, **Risk Analysis, Consumer Perception & Use, Environmental Impact**, and Market Introduction Date

JULY 28TH US FDA ANNOUNCED NEW STRATEGY



- “Strike the **right balance** between ‘**smart**’ regulation & encouraging innovation of satisfying, less harmful products.” *Mitch Zeller, J.D., Director, FDA Center for Tobacco Products, 23Aug17*



- Tobacco Control Act cannot ban a category of product.
- Therefore on 28Jul17, FDA announced that it intends to issue a number of Advance Notice of Proposed Rulemaking (ANPRM), including one to solicit additional comments and scientific data related to the patterns of use and resulting **public health impacts from premium cigars.**

What is “**smart**” regulation?

BACK TO BASICS: WHAT IS REGULATION?

- Regulation is the management of complex systems according to a set of rules.
- The complexity of the regulation should be **relative to the level of complexity** of the product or service, the size of the impact and the expected frequency of a failure.



WHY REGULATE?

Regulations can be used to:

- Control a market
- Control a society
- Create a public service or product
- Change transparency on services or products
- Manage risks, past, current or future
 - Public Health, Conduct, Fraud/Financial, Environment, Workforce
 - Etc...

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WHAT WOULD BE CONSIDERED “SMART” REGULATIONS?



- Intent is transparent
- Clearly defined and understood
- Do not produce unintended consequences
- Controls are relative to risk
- Controls are designed to achieve intended outcome
- Total benefits exceed total costs

REGULATORY FRAMEWORKS



Is there...	Pharma	Cigarettes	Machine Made Cigar	Hand Rolled Cigar
History of regulation?				
Significant Public Health Risk?				
Standardized Design?				
Product Complexity?				
Materials Control?				
Standardized Manufacture?				

REGULATORY FRAMEWORKS



Is there...	Pharma	Cigarettes	Machine Made Cigar	Hand Rolled Cigar
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Standardized Manufacture?	Yes			

REGULATORY FRAMEWORKS



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REGULATORY FRAMEWORKS



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Materials Control?	Yes	Yes	~	
Standardized Manufacture?	Yes	Yes	~	

REGULATORY FRAMEWORKS




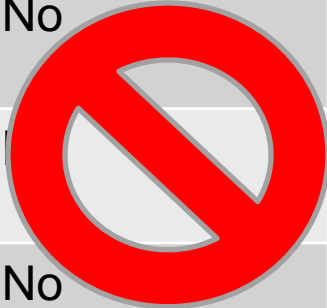



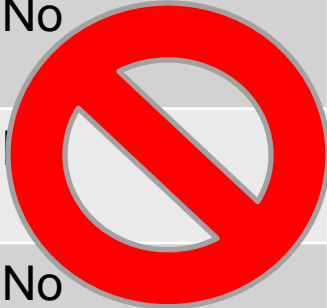



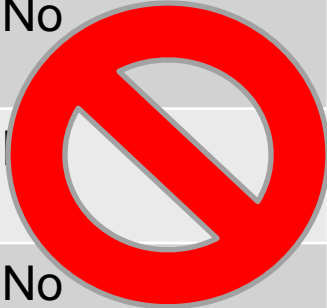


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Standardized Design?	Yes	Yes	~	No
Product Complexity?	Yes	~	~	No
Materials Control?	Yes	Yes	~	No
Standardized Manufacture?	Yes	Yes	~	No

* Relative to Total Population Risk

REGULATORY FRAMEWORKS



Is there...	Pharma	Cigarettes	Machine Made Cigar	Hand Rolled Cigar
History of regulation?	Yes	Yes	No	No
Significant Public Health Risk?	Yes	Yes	No	No
Standardized Design?	Y 	Y 	~ 	No 
Product Complexity?	Y 	~ 	~ 	No 
Materials Control?	Y 	Y 	~ 	No 
Standardized Manufacture?	Yes	Yes	~	No

PREMIUM CIGARS: WHAT ARE RISKS THAT REGULATIONS ARE AIMING TO CONTROL?

Population & Health?

Unique Consumer
Relatively small number of consumers. Worldwide: **1%**
1 billion Cigarette Smokers,
90 million MMC Smokers,
10 million Premium Cigar Smokers.

People

Consistency or Art?

Manual manufacturing process
Physical control measurements
Organoleptic controls
Product definition not standardized
Lab science still evolving.

Process

Place

Adulteration & Contamination?

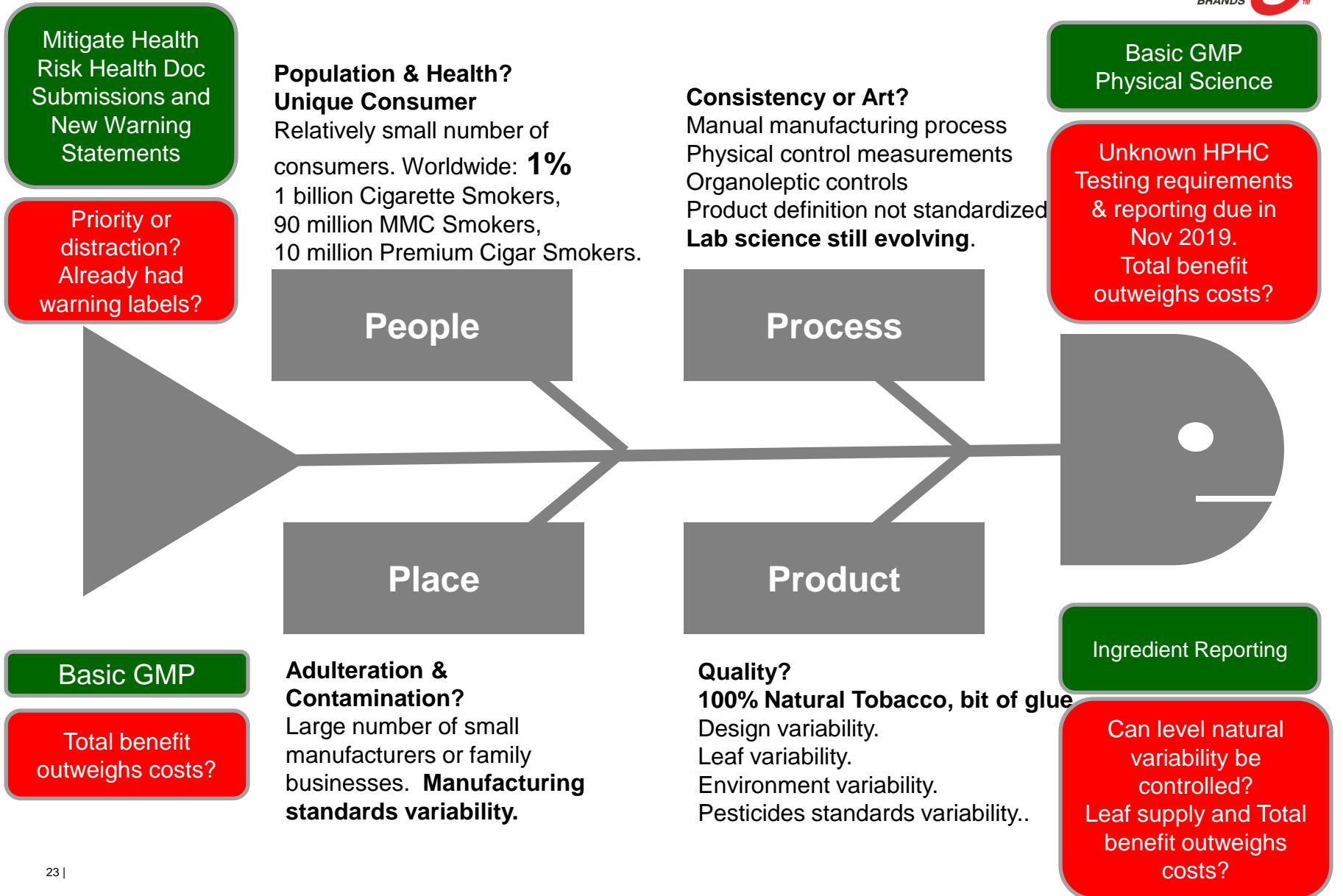
Large number of small manufacturers or family businesses. Manufacturing standards variability.

Product

Quality?

100% Natural Tobacco, bit of glue.
Design variability.
Leaf variability.
Environment variability.
Pesticide standards variability..

PREMIUM CIGARS: WHAT ARE RISKS THAT REGULATIONS ARE AIMING TO CONTROL?



SUMMARY:

Scientific community is critical responding to proposed FDA Rule-making.



Costs & Unintended Consequences

- Science is not established or rigorous and could lead to misinterpretation.
- High impact on Premium Cigar Market, small manufacturers, supply chain and farmers
- Costs to Consumer could rise
- Black-market

Benefits

- Potential increase in product consistency and limited transparency of information
- May increase a societal impression that cigars are 'regulated'

But what does that mean?

Will FDA achieve intention?

Will regulating Premium Cigars actually migrate users to less harmful products?

Most likely not.

EU & ROW approach appears to align to risk.

Current US Approach appears inconsistent to risk and to their stated intention.

REFERENCES



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