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TPE 2024 | Education

Fortify Your Future

Industry Overview: The Path Ahead

What to Watch in 2024 & Beyond

Regulations

Flavors

Products
- FDA-CTP authorization
- MRTP

Illicit trade

Business

Products
- Flavors
- Menthol
- Enforcement

Economics

Risk Management

Innovation

Operating Environment

Legal issues

Politics

Other recreational molecules

Flavors

Cigarettes → Cigars → ENDS → Oral → White Pouches et. al.

State & local actions (bans)

5 states (MA, NJ, NY, RI, CA) & Nearly 400 localities in 12 states

FDA-CTP final rule on product standards (menthol cigarettes & flavored cigars)

- March 2024 (???)*
- Mitigating factors

**HHS FY 2023 Unified Regulatory Agenda: View Rule (reginfo.gov)*

CTP product authorization

- No flavor other than tobacco authorized under PMTA alone
- High authorization standard

A little too quiet?

- Avoided trigger points to spur CTP action
- Full agenda – next target?
- Acceptable off-ramp in the absence of any other flavored products?

Synthetic nicotine

Products: by the numbers

Source: ttps://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se

PMTA's since 2021:

278 Companies with Vape/ENDS products in-market received Marketing Denial Orders from CTP equaling millions of individual SKUs

4 Companies (Logic, Reynolds, NJOY, & US Smokeless Tobacco CO.) received Marketing Granted Orders for non-traditional nicotine products

1 Brand (Verve) was authorized for market with a characterizing flavor

SE's* since 2021:

**FDA tracking extends only to the end of FY 2022*

11 Cigarette SE submissions gained authorization

40 Cigar SE submissions gained authorization

144 Pipe product SE submissions gained authorization

8 RYO product SE submissions gained authorization

11 Hookah product SE submissions gained authorization

Regulations: MRTPs

Modified Risk Tobacco Product: what is it?

Risk or exposure modification claim authorized to be made about the product	PMTA required as first step	Time-bound up to 5 years, then needs renewal
Proven to be a difficult process	In action, there are significant questions about its commercial viability	Only instance where a manufacturer can make a statement on risk & a product

Illicit Trade

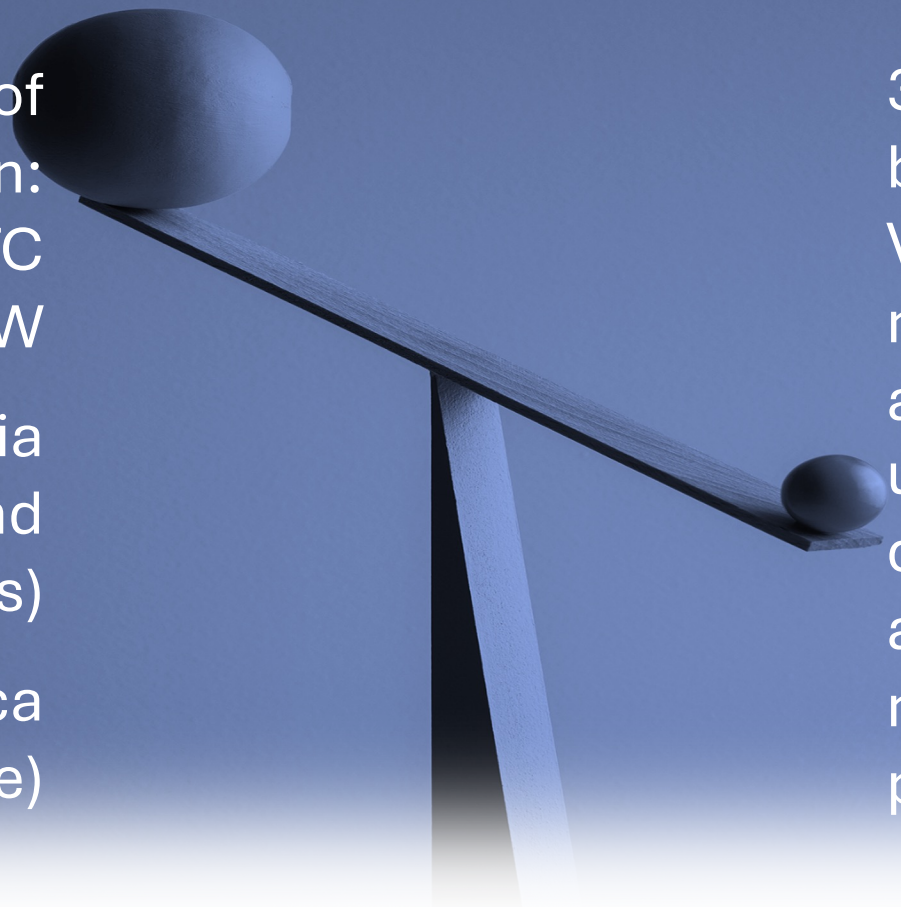
Counterfeits, Tax Avoidance, Trade in Unauthorized Products

Multiple Pathways of Market Penetration:

- DTC
- DTR or DTW

Inflows from Asia (flavored ENDS and counterfeits)

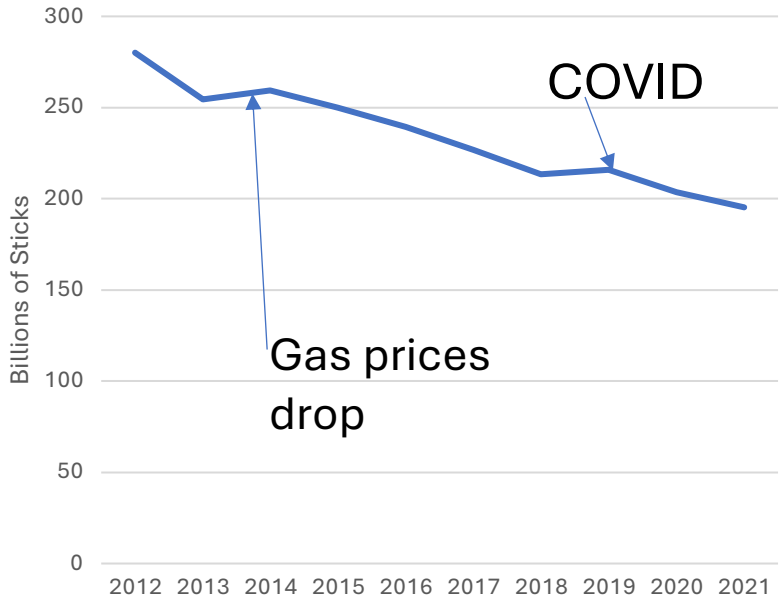
Inflows from S. America (tax avoidance)



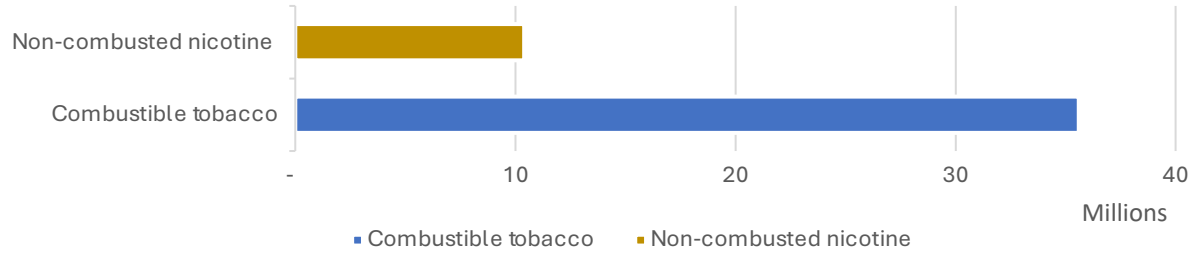
3 authorized ENDS brands (Logic, NJOY, Vuse) and an unknown number of provisionally authorized brands, all unflavored, cannot counterbalance against a large and lucrative market of unauthorized products.

Economics

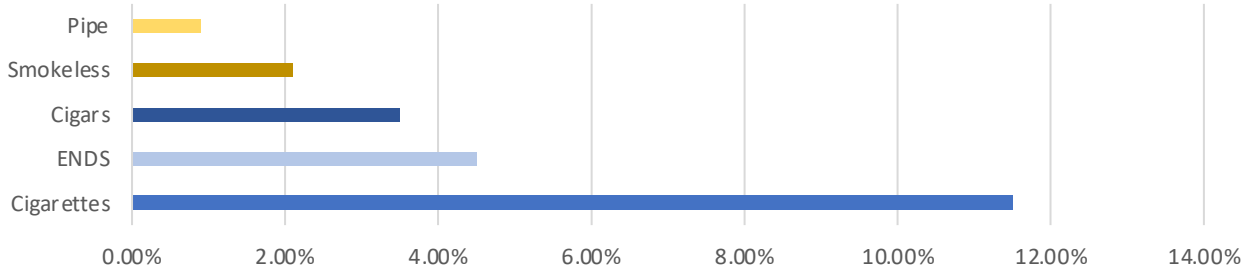
US Cigarette Volumes 2012-2021



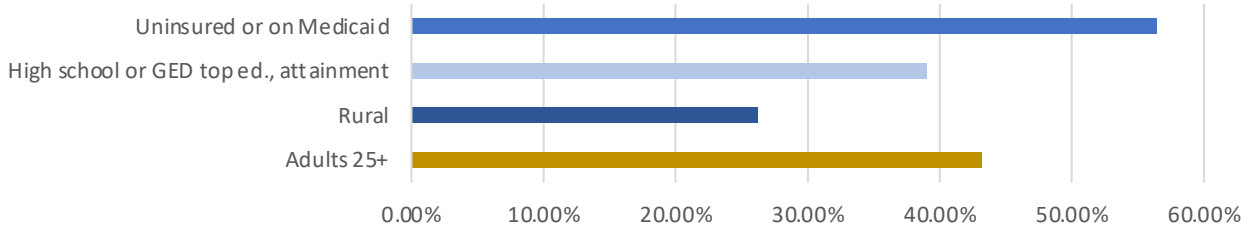
Nicotine Users in the U.S. (2021)



Total 18+ Population Nicotine Users (2021)

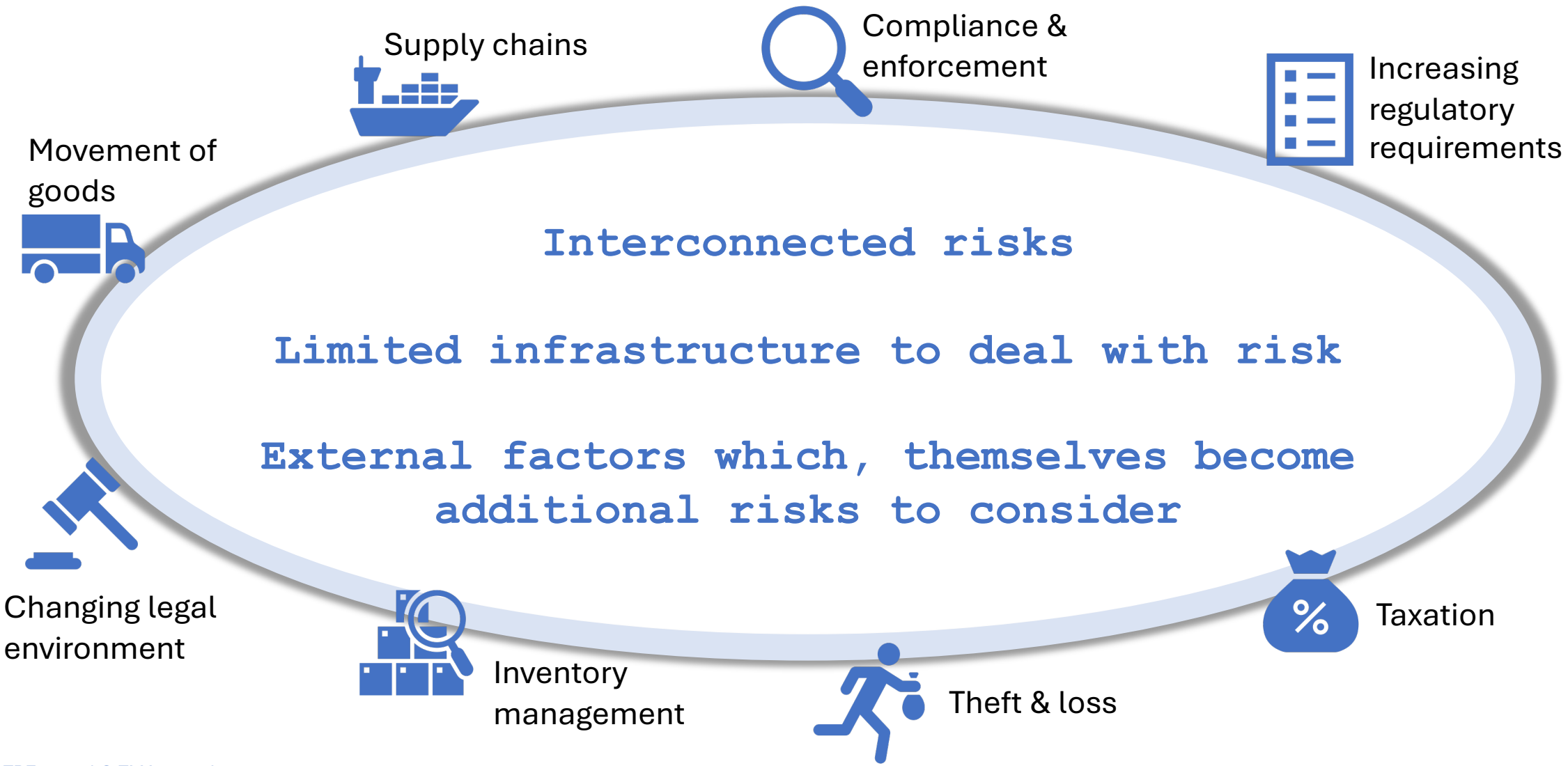


Nicotine Consumer Socioeconomic Indicators (2021)



Prevailing economic conditions, especially inflation, will be a deciding factor in 2024

Risk Management



Innovation

United States

Preauthorization is both a focus of and a constraint upon innovation

- Creates barriers to entry for new products
- Capital intensively of innovation vis-à-vis preauthorization drive consolidation of innovation:
  - Capital access and operational scale
  - Product evolution
  - Market entry
  - Number of actors
- Mismatch of products to consumer preferences (performance & illicit concerns)

Globally

Combination of consumer driven & regulatory driven innovation

- Action on disposable products
- Heated products:
  - Different markets & consumers
- More straightforward route to market
- More licit players and products (greater opportunity)
- Similar concerns to the US:
  - Regulatory action on flavors
  - Youth issues
  - Illicit trade

Operating Environment: Legal

- Circuit splits in deciding MDO legal challenges
- Product standards (?)
- Public health (?)

Operating Environment: Politics

The 2024 election will inject further uncertainty into not only the political but also regulatory process. Perhaps the effects are manifesting themselves already.

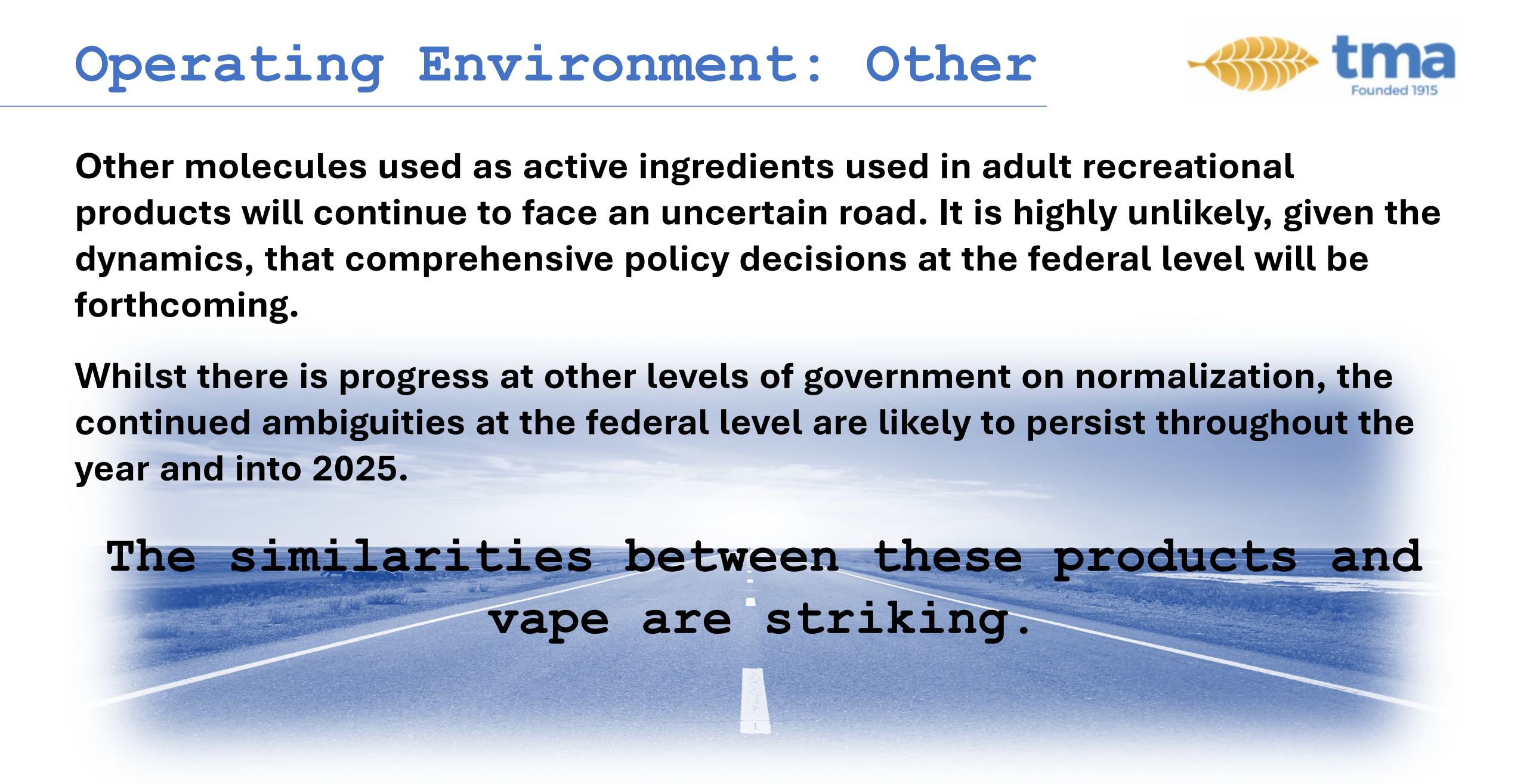
2016-2020 was an extraordinarily challenging time for the industry:

- EVALI crisis
- FDA actions
- International trade

Operating Environment: Other

Other molecules used as active ingredients used in adult recreational products will continue to face an uncertain road. It is highly unlikely, given the dynamics, that comprehensive policy decisions at the federal level will be forthcoming.

Whilst there is progress at other levels of government on normalization, the continued ambiguities at the federal level are likely to persist throughout the year and into 2025.



The similarities between these products and vape are striking.