REPORT APPROACH AND OUTLINE

General Approach

- Develop framework for report
- Identify findings from evidence presented to TPSAC
- List major points of uncertainty
- Address charge in a brief summary
- Provide recommendations for further information gathering, research and surveillance

Framework

- Adopt/modify framework in background note

Findings from materials presented to TPSAC

- Peer-reviewed literature
- Industry presentations
- Industry documents (open and commercial confidential)
- Open public hearing input
- Review of Swedish experience
- Indiana experience and youth presentations

<u>Peer-reviewed literature</u> (only products currently available)

- Constituent yields
- Abuse liability-tend to be less than that of cigts and conventional US smokeless products
- Potential health effects-info on TSNAs, nicotine, cancer risk (with limited quantification of risk) – profile looks like exclusive use of DTPs should be less hazardous than cgts also less than smokeless tobacco products marketed in US
- Consumer perception-Parascondola, Ariva perceived as being a non tobacco product – this is a general concern, not just based on the literature (limited lit on this). O'Hagerty, perception of co-use as primary use (when you can't smoke)
- Consumer response-people did not respond positively when tested (to these products)
- Constituent yields-variability across products, in nicotine, heavy metals & TSNA yields/less than cigarettes
- Product yield and delivery
- Literature on childhood poisoning-has been tracked, limited data, not many serious ingestions recorded so far

Industry presentations

- Presentations by industry reps-support denying access to children
  - Users smoke fewer cgts
  - There are a variety of products with different nicotine and TSNA yields
- Findings from 904(b) data reviews
  - Marketing as accessory items for establish smokers (or other tobacco users), used to deal with craving, in circumstances where social perceptions weigh against smoking
  - Not positioning these as smoking cessation products, albeit they are not allowed to market as such.
  - However, can be marketed as completes substitutions for cgts.

Open public hearing and public submissions

- Concern among some percentage of public that these products could be banned (maybe more so for e-cigs)
- Sense that various gov't agencies should take a more pro-active approach to providing education on individual risk (not lumping all tobacco products together) – b/c they believe it is useful for cessation
- They are concerned that people have exaggerated perception of the health risk
- These products aren't particularly liked (except maybe e-cigs)
- These products are not used alone in stopping the use of cgts.

Review of Swedish experience

- ***Context*** makes generalizing the Swedish experience difficult due to the population differences, (history of traditional snus use).
  - Includes a voluntary product standard that is adhered to by manufacturers of snus in sweden
- Distinction btx males vs. females who became exclusive snus users (i.e., males tend to switch completed, females more likely to continue to smoke).
- Exploration of Swedish data may yield additional information about dual use
- For health benefit to accrue complete substitution is required (complete sub of cigt with snus)
- 50% of snus users are naïve to tobacco when they begin using
- Labeling is different in Sweden

Indiana experience and youth presentations

- Relatively low penetration in youth market even of the products that have been around for a long time
- Packaging is very important to appeal among youth (as yet no evidence that packaging has an impact)
- VA study shows packaging influence youth perception of product
- Possibly newer products are being packed in such a way that is more appealing to youth based on lessons learned from the older products (see first bullet above) – evolution of packaging is something to monitor.
- The way that DTP are used among youth is co-use
- People seem confused (not just youth) as to what the product actually is.
- There is an appeal related to others not knowing when one is using the products

Summary

- Statement of charge
- Committee approach
- List of materials considered (but not include written reviews) and key findings
- Answer to charge
- Recommendations for further information gathering, research and surveillance