Tobacco Industry Efforts To Reduce Nicotine

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Background

- FDA issued the ANPRM for a “Tobacco Product Standard for Nicotine Level of Combusted Cigarettes” on March 16, 2018.
- FDA has expressed interest in reducing nicotine levels to 0.3, 0.4, or 0.5 mg/g in filler; about a 98% reduction from current levels.
- FDA has suggested that such levels are technically achievable by employing and/or combining several potential technical solutions


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PR Tobacco Product Standard for Nicotine Level of Combusted Cigarette

This Proposed Rule document was issued by the **Food and Drug Administration** (FDA)

For related information, **Open Docket Folder**

Action

Advance notice of proposed rulemaking.

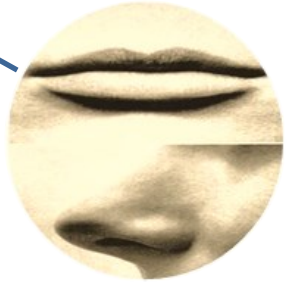
Summary

The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain in consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. Because tobe harms ultimately result from addiction to the nicotine in such products, causing repeated use and exposure to toxicant considering taking this action to reduce the level of nicotine in these products so they are minimally addictive or nonad the best available science to determine a level that is appropriate for the protection of the public health. FDA is using t "nonaddictive" in this document specifically in the context of a potentially nonaddictive cigarette. We acknowledge the potential of nicotine itself depending upon the route of delivery. As discussed elsewhere in this document, questions re respect to the precise level of nicotine in cigarettes that might render them either minimally addictive or nonaddictive f

Technical Achievability Considerations

TIME

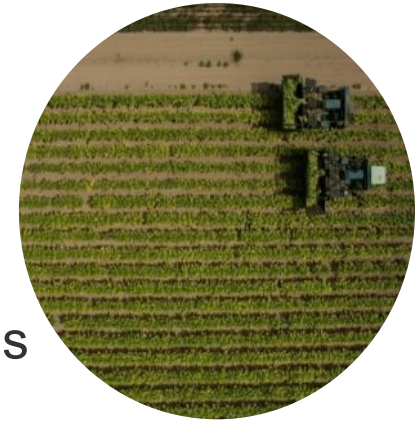
❑ Commercial Feasibility



❑ Sensorial Acceptability

FDA Proposed Solutions

Agronomic Practices



- Seedling selection
  - Impractical and inaccurate
- Increased plant population
  - Adverse effects on quality and production practices
- Eliminate topping of tobacco
  - Adverse effects on quality and production practices
- Add chemicals to influence nicotine synthesis
  - Requires USDA and EPA approval
- Tobacco treatment with biologics
  - Questionable results may not replicate at commercial scale

None of these practices approach nicotine levels of 0.3-0.5 mg/g

Tobacco Blending and Curing

- Replace “nicotine-rich” species with lower nicotine species
  - Nicotiana rustica vs Nicotiana tabacum
- Utilize lower nicotine tobacco types
  - Replacing Burley and Bright with Oriental
- Blend tobacco leaf from lower stalk positions
  - Impractical and unsustainable
- Tobacco curing
  - No significant reduction of nicotine

None of these practices approach nicotine levels of 0.3-0.5 mg/g

Chemical Extraction

- Water-based extraction (1950's)
  - Lab experiments reported up to 95% nicotine reduction
  - Abandoned due to resultant sensorial issues
- Solvent-based extractions (1960's)
  - Lab experiments reported up to 90% nicotine reduction
  - Abandoned due to resultant sensorial issues
- Steam distillation (1970's)
  - Lab experiments reported up to 90% nicotine reduction
  - Abandoned due to resultant sensorial issues

None of these practices achieve nicotine levels of 0.3-0.5 mg/g

Chemical Extraction

- Super Critical Fluid Extraction (SCFE) (1970's – 1990's)
  - Non-selective removal of multiple compounds (nicotine and flavor)
- PM USA launched 'Next' and other brands using SCFE tobacco in early 1990's and discontinued marketing in 1992
  - 1988-1989: Consumer studies
    - Feedback: bad taste, bad aftertaste, and lack of strength
  - 1990-1992: Test Market
    - Also marketed as B&H® and Merit®
  - 1993: SCFE commercial production equipment was dismantled

Product sales were discontinued due to consumer rejection

Combining Solutions

Agronomic Practices | Tobacco Blending/Curing | Chemical Extraction | Technical Achievability

Combination is not a plausible assumption

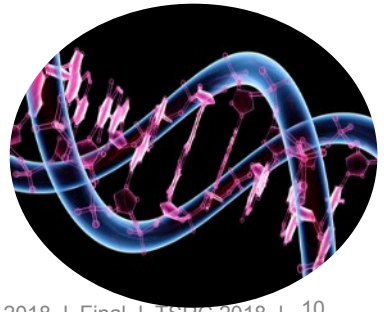
- No data currently available to prove commercial achievability
- Potential complicating factors
  - Unknown sensory impact
  - Unknown HPHC profile

Genetic Engineering

- Genetic engineering conceptually appears to be the most promising candidate among existing technologies
- Currently, there are no publically available tobacco varieties that meet FDA's suggested nicotine levels

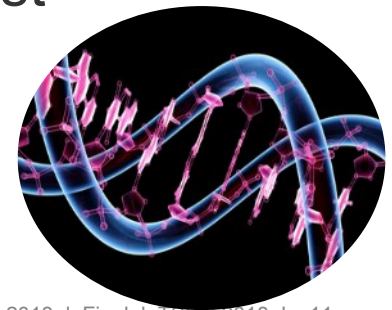
Reported Nicotine Levels for Research Tobaccos

- Conventional Breeding: 2.0 – 2.5 mg/g
  (Legg and Collins, Can J Genet Cytol, 1971, R.S. Lewis, Nicotine & Tobacco Research, 2018)
- Genetic Engineering: 0.6 – 8.3 mg/g
  (R.S. Lewis, Nicotine & Tobacco Research, 2018)



Genetic Engineering Concerns

- Poor leaf quality
- Intellectual property rights
- Genetically modified tobacco varieties (GMO) may require USDA deregulation
- Segregation of GMO tobaccos from conventional tobaccos
- State Minimum Standard Programs may need to adjust requirements for commercial production approval
- Time required for investigation and validation



GMO Tobacco - Vector 21-41

- Commercial scale production has not been validated
- Vector 21-41 is believed to be a major component of SPECTRUM® cigarettes
- Available research indicates poor taste negatively influences adult smoking perception and behavior

  (S. Dolan et.al., SRNT abstract, 2018)
- Nardone *et.al.,* reported 78% non-compliance in clinical studies

  (Nardone N et.al., Addiction, 2016)
- Impact of Vector 21-41 on HPHCs in conventional cigarettes has not been determined

Conclusion

- A product standard of 0.3-0.5 mg nicotine/g filler is currently not technically achievable
  - Commercial feasibility and sensorial acceptability
- Combination of different solutions is not yet proven to meet the FDA's suggested nicotine levels
- GMO tobaccos could be a possible solution, but require validation at commercial scale
- Impacts of GMO tobaccos on sensory and constituents profiles are unknown
- Even if achievable, significant development time would be required to meet the FDA's suggested nicotine levels

- **Further data and details:**
  ALCS's comments to the FDA's ANPRM on a Tobacco Product Standard for Nicotine Level of Certain Tobacco Products.
  http://www.altria.com/About-Altria/Federal-Regulation-of-Tobacco/Regulatory-Filing