



# Testing & Reporting Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products

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*Tobacco Science Research Conference*

*Williamsburg, VA*

*September 16, 2013*



# Outline

- Statutory requirements regarding HPHCs
- Establishing HPHC list
- 2012 HPHC reporting guidance



# Section 904(e) of FD&C Act

- By April 2012, FDA has to establish HPHC list
  - HPHCs in product and in smoke
  - FDA has to periodically revise HPHC list
  - HPHC list will include quantities by brand and subbrand for regulated tobacco products



# Section 904(a)(3) of FD&C Act

- For regulated tobacco products, manufacturers have to report HPHC quantities
  - HPHCs established by FDA
  - Reporting begins on June 22, 2012
  - Comply with regulations under section 915 of FD&C Act



# Section 904(c)(1) of FD&C Act

- Report HPHC quantities at least 90 days before introducing new tobacco product into interstate commerce
  - Comply with section 904(a)(3) requirements



# January 2011 HPHC Guidance

- HPHC: Any chemical or chemical compound in a tobacco product or present in tobacco smoke that
  - Is or potentially inhaled, ingested, or absorbed into the body
  - Causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products



# January 2011 HPHC Guidance

- Direct Harm
  - Toxicants
  - Carcinogens
  - Addictive Chemicals or Chemical Compounds



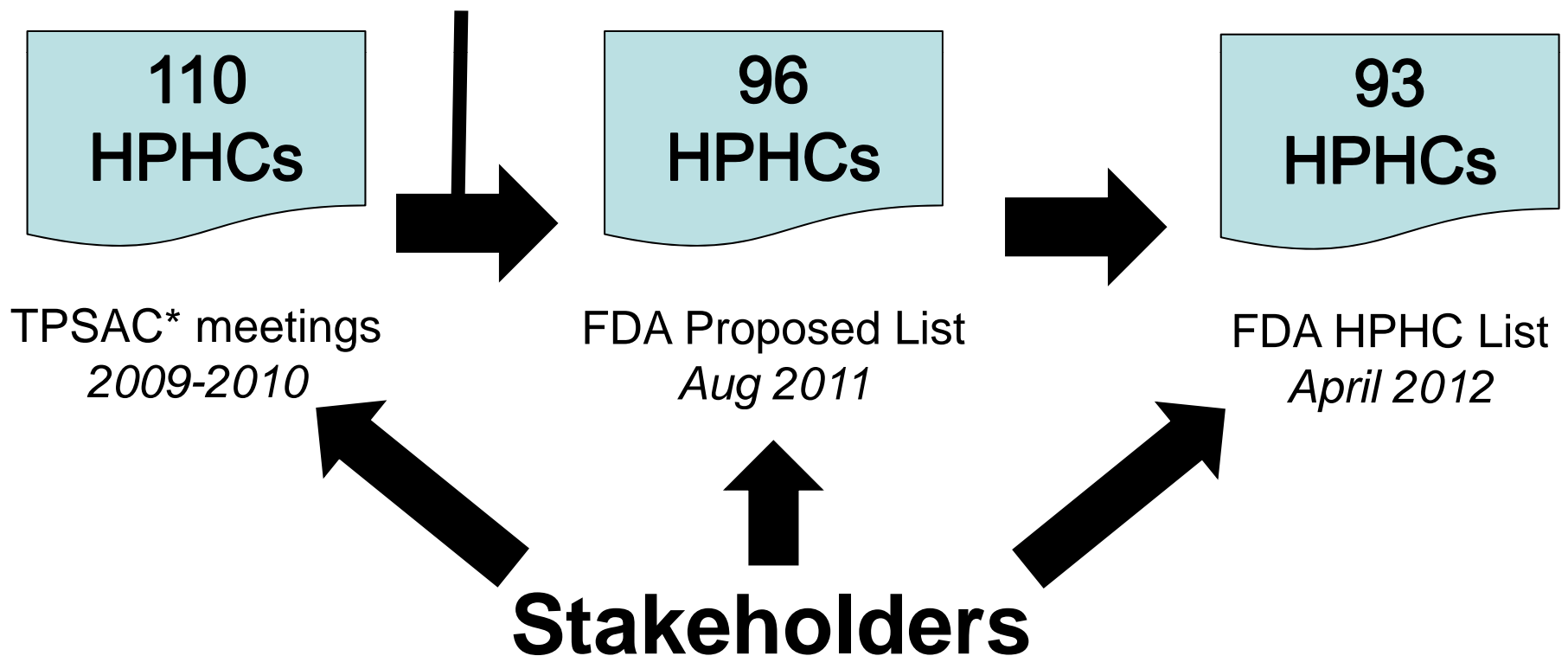
# January 2011 HPHC Guidance

- Indirect Harm
  - Potentially facilitate initiation of tobacco product use
  - Potentially impede cessation of tobacco product use
  - Potentially increase intensity of tobacco product use (frequency, amount consumed)
  - Potentially enhance the harmful effects of another tobacco constituent



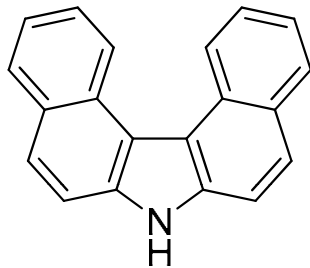
# Establishing HPHC List

HPHC  
Guidance

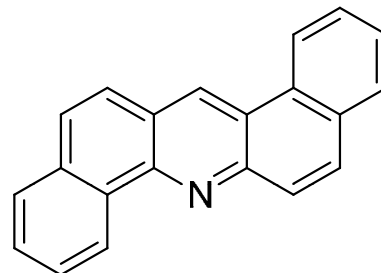


\* TPSAC: Tobacco Product Safety Advisory Committee

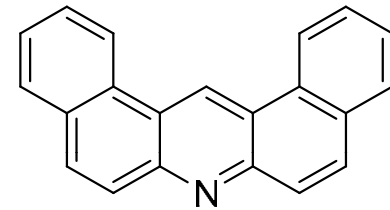
# Proposed HPHC List Modified



Dibenzo[*c,g*]carbazole



dibeno[*a,j*]acridine



dibenzo[*a,h*]acridine

- Removed 3 HPHCs based on data from contract research laboratory
  - Original 1960 data could not be repeated
  - Recent analysis did not detect in smoke from currently marketed tobacco products



# April 2012 904(a)(3) Draft Guidance

- Statutory requirement for testing & reporting HPHC quantities
- Which HPHCs to report
- Who tests and reports HPHC quantities
- When to submit reports
- What information to report
- How to submit reports

***Guidance includes recommendations***

# 904(a)(3) Draft Guidance: Which HPHCs to Report

- Abbreviated HPHC List
  - 20 HPHCs
  - Well established analytical methods
  - Representative of several chemical classes
  - May revise in the future
- If deviations from abbreviated HPHC list, then entire HPHC list required
  - FDA is only exercising enforcement discretion if abbreviated HPHC list reported



# 904(a)(3) Draft Guidance: Which HPHCs to Report

Cigarette Smoke	Smokeless Tobacco Products	Roll-Your-Own & Cigarette Filler
Acetaldehyde	Acetaldehyde	Ammonia
Acrolein	Arsenic	Arsenic
Acrylonitrile	Benzo[a]pyrene	Cadmium
4-Aminobiphenyl	Cadmium	Nicotine (total)
1-Aminonaphthalene	Crotonaldehyde	NNK
Ammonia	Formaldehyde	NNN
Benzene	Nicotine (total and free)	
Benzo[a]pyrene	NNK	

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# 904(a)(3) Draft Guidance: When & Which HPHCs to Report

- Rationale for delayed reporting date & abbreviated HPHC List
  - Short time between establishing HPHC list and beginning of reporting obligations
  - Limited internal laboratory testing abilities
  - Reliance on contract laboratories
  - Large number of tobacco products



# 904(a)(3) Draft Guidance: What to Report

- Appropriate sampling techniques
- Reproducible results
- Replicate measurements with report of mean and standard deviation



# 904(a)(3) Draft Guidance: What to Report

- Intense & non-intense smoking regimens
- Indicate linear or rotary smoking machine
- Seven replicates for most HPHCs
  - Nicotine and carbon monoxide: 20 replicates



# Conclusions

- Tobacco manufacturers are currently required to test & report HPHC quantities
  - Abbreviated HPHC list
- No testing requirements but FDA recommendations in guidance documents
- FDA efforts regarding HPHC testing & reporting has involved stakeholders
  - Encourage stakeholders to share information with FDA