OVERVIEW OF TOBACCO PRODUCT MANUFACTURING PRACTICE (*TPMP*) PROPOSED REGULATION

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- The information is provided to TPSAC to aid the Committee in its evaluation of the proposed regulation.

- Overview
- Objectives
- Protect Public Health
- Compliance with FD&C Act
- Scope
- Framework
- Provisions of Proposed Rule
- Topics for Discussion

OVERVIEW

TPMP is a **foundational rule** that will help protect public health and assist with CTP's authorities, including:

- Premarket review
- Tobacco product standards

OBJECTIVES

TPMP ≠ tobacco product is safe

- Minimize or prevent product problems and health issues not normally associated with use of tobacco product

Statutory objectives:

- Protect public health
- Tobacco products are in compliance with chapter IX of FD&C Act

PROTECT PUBLIC HEALTH

Minimize or prevent and investigate product problems and health issues not normally associated with use of tobacco product

Ensure tobacco products are manufactured to conform to established specifications

Identify and investigate nonconforming tobacco products

Prevent contamination of tobacco products

COMPLIANCE WITH FD&C ACT

Modifications to new and pre-existing tobacco products

Other provisions of FD&C Act

- Listing, testing, and reporting of ingredients and additives
- Labels, labeling, and packaging

Establish tracing of all components or parts, ingredients, additives, and materials, as well as each batch of distributed finished or bulk tobacco product

Adulteration and Misbranding

SCOPE

Finished tobacco product manufacturers

Bulk tobacco product manufacturers

- Specification developers
- Contract manufacturers
- Repackagers/relabelers

FRAMEWORK

Umbrella approach (flexible requirements)

Manufacturers must comply with requirements applicable to their operations

Small Tobacco Product Manufacturers

- Effective Date: 2-years
- Compliance Date for small tobacco product manufacturers: 4 additional years after 2-year effective date = total 6 years (as required by FD&C Act)
- Petitions for Exemptions and Variances

PROVISIONS OF PROPOSED RULE

Subpart	Sections	
Management System Requirements	Organization and Personnel Corrective & preventive actions	Tobacco product complaints
Buildings, Facilities, & Equipment	Personnel practices Equipment	Buildings, facilities & grounds Environmental controls
Design & Development Controls	Design & development activities	Master manufacturing record
Process Controls	Purchasing controls Production processes & controls Production record Nonconforming tobacco product Reprocessing & rework	Acceptance activities Laboratory controls Sampling Returned tobacco product
Packaging & Labeling Controls	Packaging & labeling controls Manufacturing code	Repackaging & relabeling Warning plans
Handling, Storage, & Distribution	Handling & storage	Distribution
Recordkeeping & Document Controls	Recordkeeping & document control requirements	
Exemptions & Variances	Exemptions & variances Petition for an exemption or variance Referral to TPSAC	Petition determination Hearing

TOPICS FOR DISCUSSION

1. The proposed scope of the rule covers finished and bulk tobacco product manufacturers, including specification developers. Does the committee have any recommendations on the scope, including expanding the scope?
2. Does the committee have any recommendations or comments on the “umbrella” approach that proposes requirements in flexible terms to enable manufacturers who are subject to the rule to establish procedures that are appropriate for their specific products and operations?
3. Does the committee have any recommendations on the product specifications that FDA proposes to require in the MMR?
4. Does the committee have any recommendations on the proposed design and development activities and risk management process to control risks associated with finished and bulk tobacco product and its production processes, packing, and storage?
5. Does the committee have any additional recommendations on the requirements of the proposed rule?