

NATO

**Tobacco Legislative &
Regulatory Review**

Topics

- **Local Tobacco Issues and New Initiatives**
- **State Legislative Update**
- **FDA ANPRMs (Nicotine, Flavors & Premium Cigars)**
- **New FDA Health Warning Statement**
- **FDA: Menthol, Flavored Cigars and E-Cigarettes**
- **FDA MRTP Applications**

Local Tobacco Ordinances (2018-19)

Arizona

Massachusetts

California

Minnesota

Colorado

New Hampshire

Florida

New York

Georgia

Ohio

Idaho

Pennsylvania

Illinois

Rhode Island

Kansas

Texas

Maine

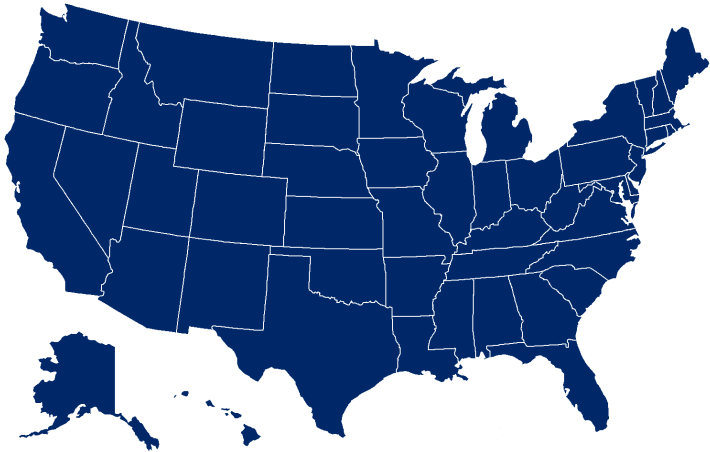
Virginia

Local Restrictions

- **Flavored Tobacco Product Sales Bans**
- **Menthol, Mint and Wintergreen**
- **Cigar Minimum Packaging/Pricing**
- **Higher Legal Age to Purchase**
- **Local Cigarette/OTP Taxes**
- **Limit on Number of Retail Licensees**

New Local Initiatives

National Response Network



**NATIONAL LOCAL
ADVOCACY ALLIANCE**

National Response Network

- **Objective: Expand Capacity to Respond to Local Tobacco Ordinances**
- **60+ State and National Associations**
- **Network Sends Ordinance Alerts**
- **Associations Engage Their Members to Oppose Local Ordinances**

NLAA

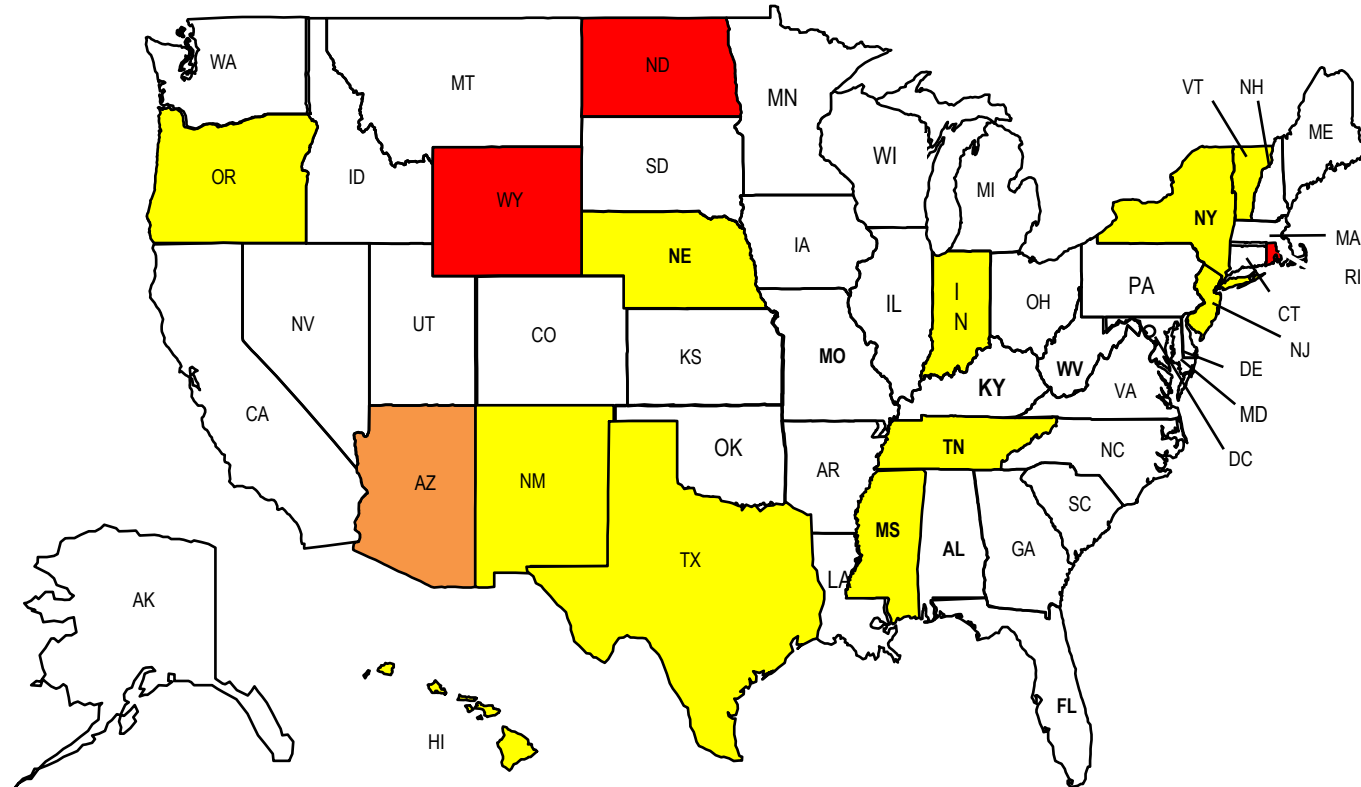
- **New Local Issue Website (www.nlaausa.org)**
- **Proposed Ordinance Information**
- **“Take Action” Page to Send E-Mails**
- **Library of Enacted Ordinances**
- **Sign Up for Local Ordinance Alerts**

Relationship Building

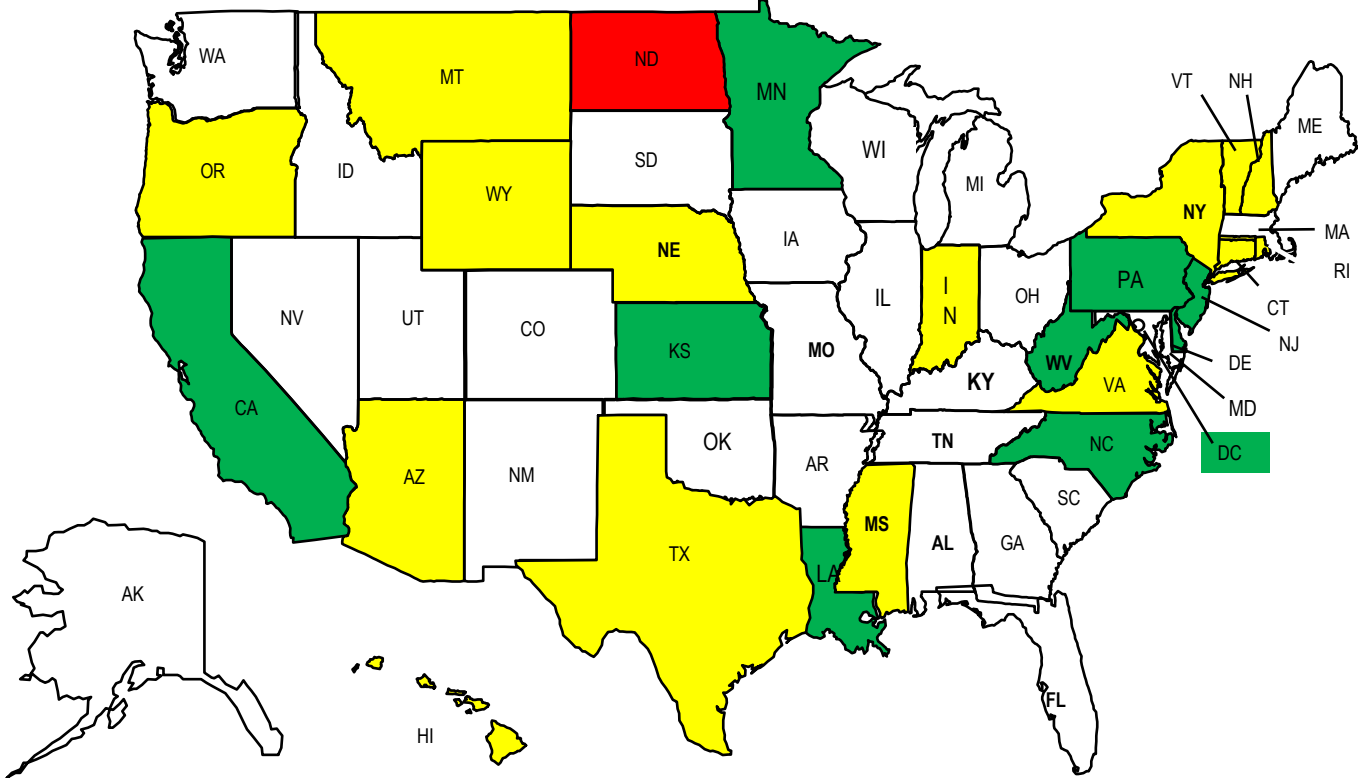
- **What Is Relationship Building?**
- **Critical to Preventing or Stopping Ordinances**
- **How to Build a Relationship**
 - **Who Are Your Local Officials?**
 - **Extend a Store Tour Invitation**
 - **Meet at Local Official's Office**
 - **If Ordinance is Proposed, Become Engaged**

2019 State Legislative Bills

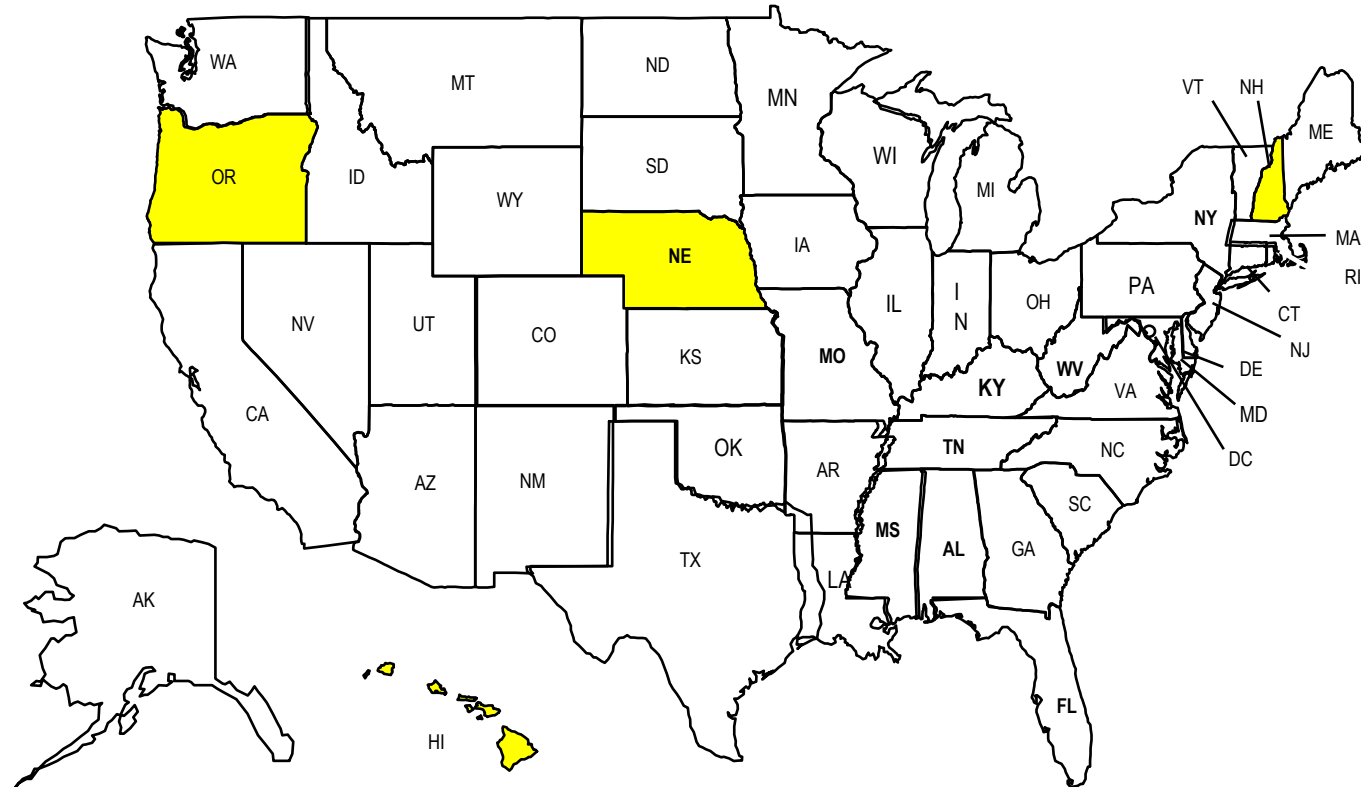
2019 Proposed Cigarette/OTP Tax Bills



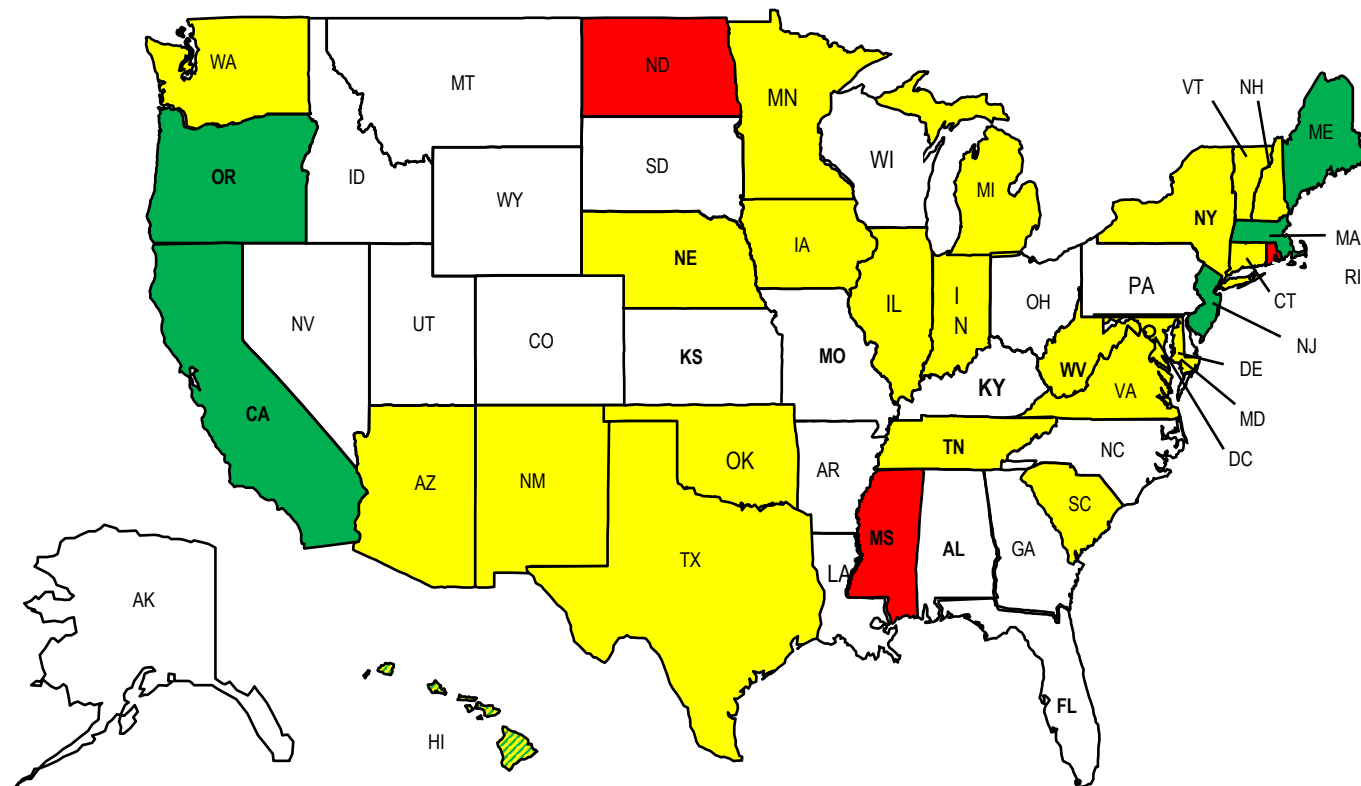
2019 Proposed E-Cigarette/Vapor Tax Bills



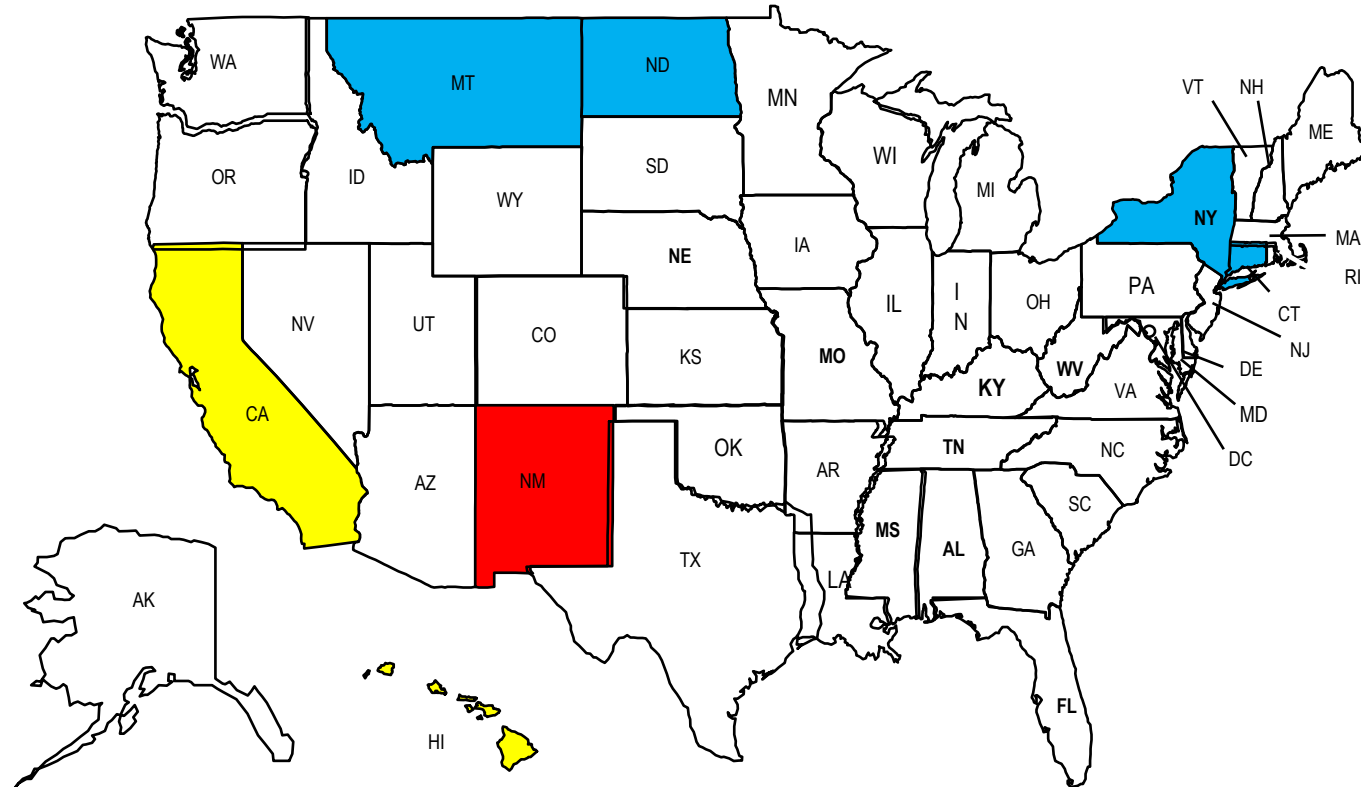
2019 Proposed Cigar Tax Bills



2019 Legal Age To Purchase Bills



2019 Proposed Flavor Restrictions/Ban Bills



Relationship Building

- **Also Applies to State Tobacco Issues**
- **Critical to Preventing or Stopping Bills**
- **Build a Relationship**
- **NATO Assists with E-Mail Action Alerts**
- **State Associations Oppose Tobacco Bills**



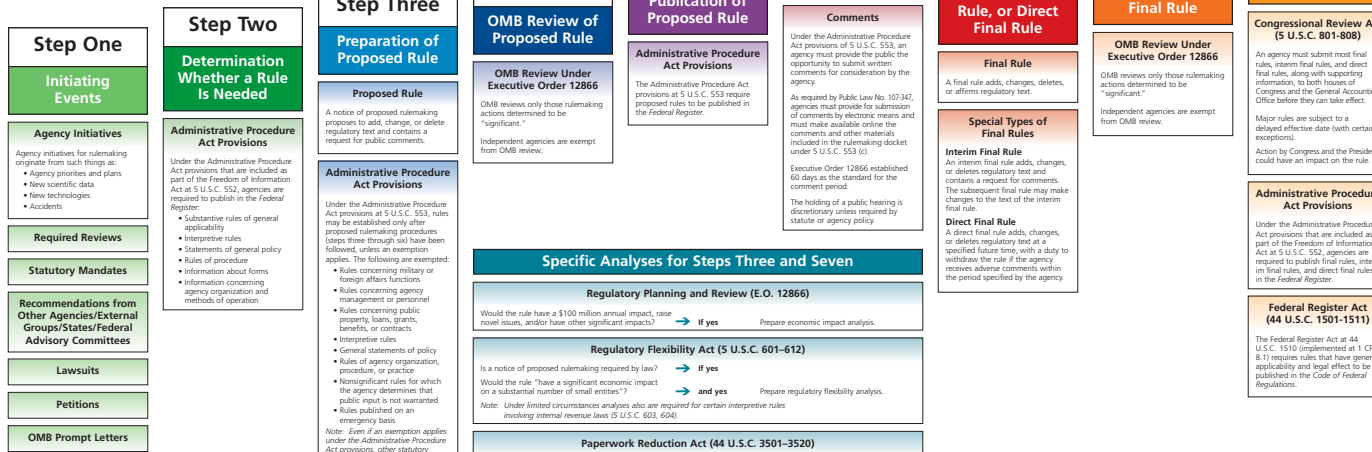
Actions and Regulations Update

FDA Issues Three ANPRMs

- **What Is An ANPRM?**
 - **Advanced Notice of Proposed Rulemaking**
 - **Seeks Public Comments**
 - **FDA Seeks Studies, Information and Data**
- **Third Step in Nine Step Process**
- **FDA Reviews Comments to Decide Whether or Not to Draft a Rule**

The Reg Map

Informal Rulemaking



Using The Reg Map

The Reg Map is based on general requirements. In some cases, more stringent or less stringent requirements are imposed by statutory provisions that are agency specific or subject matter specific. Also, in some cases more stringent requirements are imposed by agency policy.

In a typical case, a rulemaking action would proceed from step one through step nine with a proposed rule and a final rule.

However, if a rulemaking action is exempt from the Administrative Procedure Act provisions (explained under step three) or under other statutory authority, an agency may:

- promulgate a final rule omitting steps three through six, or
- promulgate an interim final rule omitting steps three through six, but providing a comment period and a final rule after step nine.

Also, if an agency determines that a rule likely would not generate adverse comment, the agency may promulgate a direct final rule, omitting steps three through six, but with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.



Experts in drafting rulemaking documents and preparing supporting analyses

Visit us at www.regsupport.com. Also, check out www.commentsworks.com for a faster, cheaper, and better way to respond to public comments on proposed rules.

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Specific Analyses for Steps Three and Seven

<p>Regulatory Planning and Review (E.O. 12866)</p> <p>Would the rule have a \$100 million annual impact, raise novel issues, and/or have other significant impacts? → If yes Prepare economic impact analysis.</p>
<p>Regulatory Flexibility Act (5 U.S.C. 601-612)</p> <p>Is a notice of proposed rulemaking required by law? → If yes Would the rule "have a significant economic impact on a substantial number of small entities"? → and yes Prepare regulatory flexibility analysis. <i>Note: Under limited circumstances analyses also are required for certain interpretive rules involving internal revenue laws (5 U.S.C. 603, 604).</i></p>
<p>Paperwork Reduction Act (44 U.S.C. 3501-3520)</p> <p>Does the rule contain a "collection of information" (reporting, disclosure, or recordkeeping)? → If yes Prepare information collection clearance package for OMB review and approval, and prepare request for public comments.</p>
<p>Unfunded Mandates Reform Act (2 U.S.C. Chs. 17A, 25)</p> <p>Does the rulemaking process include a proposed rule? → If yes Does the rule include any Federal mandate that may result in the expenditure (direct costs minus direct savings) by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually)? → and yes Prepare unfunded mandates analysis (unless an exclusion applies).</p>
<p>Federalism (E.O. 13132)</p> <p>Is the rule a discretionary rule that has federalism implications and imposes substantial unremunerated direct compliance costs on State and local governments? → If yes Prepare federalism summary impact statement. Does the rule have federalism implications and preempt State law? → If yes Prepare federalism summary impact statement.</p>
<p>Indian Tribal Governments (E.O. 13175)</p> <p>Is the rule a discretionary rule that has tribal implications and imposes substantial unremunerated direct compliance costs on Indian tribal governments? → If yes Prepare tribal summary impact statement. Does the rule have tribal implications and preempt tribal law? → If yes Prepare tribal summary impact statement.</p>
<p>National Environmental Policy Act (42 U.S.C. 4321-4347)</p> <p>Is the rule categorically excluded from review? → If no Does the rule constitute a major Federal action that could significantly affect the quality of the human environment? → and yes Prepare environmental assessment or environmental impact statement, as appropriate.</p>
<p>National Technology Transfer and Advancement Act (15 U.S.C. 272 note)</p> <p>Does the rule contain provisions for which the use of voluntary standards is applicable? → If yes Adopt voluntary consensus standards or explain why not.</p>
<p>Governmental Actions and Interference with Constitutionally Protected Property Rights (E.O. 12630)</p> <p>Does the rule regulate private property use for the protection of public health or safety? → If yes Prepare takings analysis. Is the rulemaking a proposed regulatory action that has takings implications (other than regulating private property for the protection of public health and safety)? → If yes Prepare takings analysis.</p>
<p>Protection of Children from Environmental Health Risks and Safety Risks (E.O. 13045)</p> <p>Is the rulemaking a "covered regulatory action"? → If yes Prepare analysis of the environmental health or safety effects on children.</p>
<p>Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)</p> <p>Is the rulemaking action a "significant energy action"? → If yes Prepare statement of energy effects.</p>

Drafting Requirements for Rulemaking Documents

<p>Regulatory Planning and Review (E.O. 12866)</p> <p>Rulemaking documents must comply with the specified regulatory philosophy and principles of regulation.</p>
<p>Civil Justice Reform (E.O. 12988)</p> <p>Rulemaking documents must be written in clear language designed to help reduce litigation.</p>
<p>Presidential Memorandum on Plain Language (63 FR 31885)</p> <p>Rulemaking documents must comply with plain language principles.</p>
<p>Federal Register Publications</p> <p>Rulemaking documents must comply with the Federal Register regulations (1 CFR). Additional guidance and requirements are contained in the Federal Register's Document Drafting Handbook.</p>

Agendas for Rules Under Development or Review

<p>Unified Regulatory Agenda</p> <p>The Unified Regulatory Agenda provides information concerning agency rules under development or review. The Unified Regulatory Agenda is published in the Federal Register in the spring and fall of each year.</p>
<p>Regulatory Plan</p> <p>The Regulatory Plan provides information concerning the most important significant regulatory actions that the agency is planning to take. The Regulatory Plan is published in the Unified Regulatory Agenda in the fall of each year.</p>
<p>Regulatory Flexibility Agenda</p> <p>The Regulatory Flexibility Agenda provides information concerning any rule that an agency expects to prepare or promulgate that is likely to have a significant economic impact on a substantial number of small entities. Agency regulatory flexibility agendas are published as part of the Unified Regulatory Agenda in the spring and fall of each year.</p>

ANPRM on Lowering Nicotine

- **Maximum Level of Nicotine in Cigarettes**
- **Requires a Product Standard**
- **May Reduce Nicotine Yield by 95%**
 - **From 1.1 mg/cig down to .02 mg/cig**
 - **FDA Cannot Reduce Nicotine to Zero**
- **Possibly Extend Nicotine Limit to all Tobacco Products**

ANPRM on Flavors

- **Seeking Information on Role of Flavors**
- **Role in Initiation of Tobacco Use**
- **What Flavors Appeal to What Ages**
- **Dual Use of Cigarettes/Flavored Products**
- **May Consider Banning Certain Flavors**
- **Should Flavor Ban Apply to All Products?**

ANPRM on Premium Cigars

- **Seeking a Definition of Premium Cigar**
- **Use Patterns of Premium Cigar Smokers**
 - Age When Smoking Premium Cigars Began**
 - Frequency of Smoking Premiums**
 - Is Use Seasonal (e.g., Summer)?**
- **Will Cigarette Smokers Switch to Premium Cigars if Nicotine Lowered?**

FDA Health Warning Statements

- **New Addictiveness Warning Statement**
**“WARNING: This product contains nicotine.
Nicotine is an addictive chemical.”**
- **Packaging and Ads for RYO, E-Vapor, Hookah**
- **Manufacturers: On Packages as of 8/10/18**
- **Advertising: POS, Displays, Posters, Signs,
Newspapers, Magazines, Websites, E-Mails, TV,
Radio and Social Media**

Format for Warning on Advertisements

- **Appear on Upper Portion of Ad**
- **Occupy at least 20% of Total Ad Area**
- **At Least 12 Point Bold Helvetica or Arial Font**
- **Black Text/White Background or Reverse**
- **Capitalized and Punctuated**
- **Surrounded by Rectangular Border**

Cigar and Pipe Warnings

- **Three Cigar Associations Sued FDA on Cigar Regulations and Warning Statements**
- **Court: Upheld FDA Regulation of Cigars**
- **On Appeal, Injunction Against Enforcement of Cigar and Pipe Tobacco Warnings**

FDA: Menthol Ban

- **FDA Plans to Issue Regulation Banning Menthol in Cigarettes and Cigars**
- **TPSAC Considered Menthol Cigarette Ban**
- **Requires Adoption of Product Standard**
- **9 Step Regulation Process Applies**
- **Timetable: Up to Two or More Years**

FDA: Flavored Cigar Ban

- **FDA Plans to Issue Regulation Banning Flavors in All Cigars**
- **Previously Announced in August, 2016**
- **9 Step Regulation Process Applies**
- **Timetable: Up to Two Years**

FDA: E-Cigarette Actions

- **November, 2018 Announcement**
- **Considering Flavored E-Cigarette Restrictions**
- **Considering Sales in Age-Restricted Stores Only**
- **FDA Cannot Limit Product Sales to Certain Stores**
- **Flavor Ban Would Require Nine Step Process**

FDA: E-Cigarette Actions

- **FDA Guidance Document May be Released**
- **Guidance Cannot Enact New Restrictions**
- **Meeting on December 19, 2018**
- **NATO Proposed FDA-Industry Working Group**

FDA: MRTTP Applications

- **What is a MRTTP Application?**
- **Demonstrate Lower Health Risk**
- **TPSAC Hearings Last Week (General Snus and Copenhagen Snuff Fine Cut)**
- **Camel Snus MRTTP Application Pending**



NATO

Questions