

An Update on the FDA's Tobacco Control Act: 2010-12



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FCTC and U.S. Law

FCTC Checklist:

- ✓ (Article 5) General Obligations
- ✓ (Article 6) Price and Tax Measures [SCHIP]
- ✗ (Article 8) Protection from ETS [State/Local]
- ✓ (Article 9) Contents of Tobacco Products [FDA]
- ✓ (Article 10) Tobacco Product Disclosure [FDA]
- ✓ (Article 11) Packaging & Labeling of Tobacco Products [FDA]
- ✓ (Article 12) Education, Communication, Training & Public Awareness [Health Care]
- ✓ (Article 13) Tobacco Advertising, Promotion & Sponsorship [FDA]
- ✓ (Article 15) Illicit Trade in Tobacco Products [CCTA, PACT Act, FDA/GAO...STOP?]
- ✓ (Article 16) Sales to and By Minors [FDA, State]
- ✓ (Article 19) Liability [MSA, Progeny Engle, History]



The Family Smoking Prevention and Tobacco Control Act (HR 1256)

- HR 1256 was signed by President Obama on **June 22, 2009**.
- HR 1256 grants the US Food & Drug Administration (FDA) the authorization to regulate the manufacture, sale and distribution of tobacco products.



FSPTCA – Implication for Tobacco Growers

- The FDA cannot directly affect tobacco growing or its practices.
- Indirectly, the FDA influences leaf tobacco as they have control over manufacturer supplies. This includes the pesticide/herbicide issue.



Tobacco Product Scientific Advisory Committee (TPSAC)

Formed in March 2010 and composed of 12 members all of whom are required to have knowledge in at least one of “medicine, medical ethics, science, or technology involving the manufacturer, evaluation or use of tobacco products”:

7 from the medical field [**Jonathan Samet, Neal L. Benowitz, Mark S. Clanton, Dorothy K. Hatsukami, Thomas E. Eissenberg, 2 vacancies**]

1 from government
[**Karen L. DeLeeuw**]

1 from the general public
[**Patricia Nez Henderson**]

1 from tobacco manufacturing (non-voting)
[**Jonathan D. Heck, Lorillard Tobacco Co.**]

1 from small tobacco manufacturing (non-voting)
[**John H. Lauterbach, Lauterbach & Associates, LLC**]

1 from tobacco growers (non-voting)
[**Arnold Hamm**]



TPSAC Issues

(1) Menthol Report – 7 meetings throughout 2010-11

Report released March 18, 2011

Report approved by TPSAC July 21, 2011.

TPSAC Recommendation – **Menthol be banned as a characterizing flavor in cigarettes.**

(2) Tobacco Constituents Subcommittee – 2 meetings

Listed 106 “harmful” constituents in cigarette smoke.

(3) Dissolvable Tobacco Products Report – 1 meeting

Meeting scheduled for January 18-20, 2012 and in early March.

Report to be released by March 22, 2012.



Major FSPTCA Changes So Far

- (1) **The Secretary of Health and Human Services begin assessing quarterly fees on tobacco manufacturers and importers (June 22, 2009)**
- (2) **Flavored cigarette ban (September 22, 2009)**
- (3) **Cigarette manufacturers submit list of all additives by brand/subbrand/quantity [e-submitter tool] (December 22, 2009)**
- (4) **Descriptor (“light”, “mild”, “low”) ban on cigarettes (June 22, 2010)**
- (5) **“Substantial equivalence” registration begins (January 2011).**
- (6) **CTP coordinates with States concerning tobacco retailer inspections to prevent sales to minors.**



FSPTCA Timeline

Beginning June 22, 2011

“A tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a **pesticide chemical residue** that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.”

Currently under either USDA or EPA law, **there are no established tolerance limits for pesticide residues that apply to domestically grown tobacco.**



Proposed Graphic Cigarette Warning Labels for Packages and Advertisements

- **First Draft issued November 10, 2010**
- **Public comment period ended January 9, 2011**
- **9 textual warning statements in total**
- **Final regulations issued June 21, 2011**



Proposed Graphic Cigarette Warning Labels for Packages and Advertisements

**WARNING:
Cigarettes
are
addictive**



**WARNING:
Cigarettes
cause fatal
lung disease**

**WARNING:
Tobacco smoke
can harm
your children**





Proposed Graphic Cigarette Warning Labels for Packages and Advertisements

**WARNING:
Cigarettes
cause cancer**



**WARNING:
Smoking during
pregnancy
can harm your
baby**

**WARNING:
Cigarettes cause
strokes
and heart disease**





Proposed Graphic Cigarette Warning Labels for Packages and Advertisements

**WARNING:
Smoking can
kill you**



**WARNING:
Quitting
smoking now
greatly reduces
serious risks to
your health**

**WARNING:
Tobacco smoke
causes fatal
lung disease in
nonsmokers**





Proposed Graphic Cigarette Warning Labels for Packages and Advertisements

On November 7, 2011, US District Judge Richard Leon ruled in favor of the cigarette makers and granted a preliminary injunction against the graphic labels, saying the companies are likely to prevail on First Amendment grounds.

“It is abundantly clear from viewing these images that the emotional response they were crafted to induce is calculated to provoke the viewer to quit, or never to start smoking -- an objective wholly apart from disseminating purely factual and uncontroversial information,” Judge Leon said.



FSPTCA Timeline

By April 22, 2012

(1) The CTP to issue its list of **harmful constituents** in cigarette smoke.

(2) The CTP to issue regulations on the **promotion and marketing of the remote sales** of tobacco products.

(3) The CTP to issue regulations on the **scientific evidence** required for the review of modified risk products.

(4) The CTP to issue regulations allowing **single applications** for a new and modified risk product.

May 21-23, 2012

TMA's Annual Meeting and Conference



FSPTCA Timeline

By June 22, 2012

(1) Initial draft for regulations for manufacturing restrictions/Good Manufacturing Practices (GMP) to be released by FDA-CTP.

(2) Cigarette manufacturers to test/report constituents, ingredients, and additives. (?)

(3) CTP to issue initial report to Congress on how it will be regulating MRTP's to best achieve its public health objective.

Beginning June 22, 2012

Cigarette manufacturers must submit a list of all constituents identified as “potentially harmful.”



FSPTCA Timeline

By September 22, 2012

(1) Cigarette and roll-your-own tobacco packages must place **required color graphic warnings statements** on labels and advertisements. (?)

(2) Cigarette packages must place the statement **“Sale only allowed in United States”** on labels and shipping containers.

(3) Cigarette packages must place **name/address, quantity, domestic/foreign leaf percentage statements** on labels.



THANK YOU

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