

The Family Smoking Prevention and Tobacco Control Act's Grant of Authority to the FDA and the Impact on the Grower

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The Act

- The Act governs all manufacturers and importers of tobacco products including cigarettes, smokeless and roll your own
- The Act does not currently include cigars but the FDA has the authority to add them by regulation – no new statute is required
- The Act grants FDA authority to dictate standards for tobacco products including nicotine levels (except it cannot be zero) and methods of production

The Exemptions

- The Act specifically limits the Act's jurisdiction over tobacco warehouses and tobacco growers. (Sec. 901(c)(2)(A)) It states the following:
- (2) Limitation of Authority –
- (A) In General – The provisions of this chapter shall not apply to tobacco leaf that is not possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco **growers, tobacco warehouses, and tobacco grower cooperatives**, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of the producer.
- (Id.; Emphasis added)

Tobacco Warehouse

- The term tobacco “warehouse” is defined (in part) in the Act to mean any person:
- (i) who –
 - (I) removes foreign material from tobacco leaf through nothing other than a mechanical process;
 - (II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist;
 - or
 - (III) de-stems, dries, and packs tobacco leaf for storage and shipment;
- (ii) who performs no other actions with respect to tobacco leaf; and
- (iii) who provides to any manufacturer to who the person sells tobacco all information related to the person’s actions described in clause (i) that is necessary for compliance with this Act.
- (Sec. 900(21)(A))

The Exemption Does Not Apply to Growers That Also Manufacture

The Act says that the FDA may regulate an entity that grows tobacco if it also produces tobacco products and/or imports tobacco products. If an entity is covered by the Act the FDA can regulate that entities operation including growing tobacco.

Senate Colloquy

- The limitation on regulating tobacco warehouses and growers was specifically addressed on the U.S. Senate floor by Senator's Warner and Dodd when the Act was being debated. Here is an excerpt of their colloquy from the debate:
- REGULATING TOBACCO WAREHOUSES
- Mr. WARNER. Mr. President, the bill before us grants standby authority to the Secretary of Health and Human Services to regulate ``tobacco warehouses." Because the bill already draws a bright line between tobacco companies that actually manufacture tobacco products and those, including growers and ``tobacco warehouses," that do not manufacture, I would expect that the Secretary would utilize the standby authority to regulate tobacco warehouses only under unforeseen and unanticipated circumstances that give rise to public health concerns.
- Mr. DODD. That is my general understanding of the provision.
- Mr. WARNER. I thank the Senator.

FDA May Regulate Tobacco Warehouses In The Future

The Act provides, however, that the FDA has the authority to determine by formal rulemaking that the activities of tobacco warehouses should be regulated. The idea is that whatever the FDA needs to do to regulate tobacco products can be done without regulating warehouses. If for some reason the FDA decides that it must regulate warehouses it can do so by promulgating a formal rule.

Tobacco Fees

- The user fees under the Act are collected from “manufacturers and importers of tobacco products” based on market share. (Sec. 919) Again, the purpose of the Act is to regulate tobacco product manufacturers and those entities that sell consumer products.
- Tobacco warehouses and growers are not subject to those fees because they do not sell tobacco products and thus do not have any tobacco product market share.
- The fees will be 712 million in 2019 and subsequent years

Reporting of Ingredients

- The tobacco product manufacturers are reporting the ingredients of their respective products including the type of tobacco used. The Guidance regarding ingredients says that “FDA intends to enforce ingredient listing requirement” on:
 - manufacturers and importers of cigarettes, smokeless tobacco, and roll-your-own tobacco that are ready for consumer use; and
 - manufacturers and importers of tobacco, filters, papers, or pouches, whether such products are intended for further manufacturing or are ready for consumer use. This includes papers, tobacco, and filters sold separately, in kits (such as for roll your own tobacco), or as part of accessories.

The Ingredient Report Must Include Tobacco Type

The Ingredient Guidance specifically addresses “leaf tobacco” (i.e. unmanufactured tobacco) as an ingredient of a tobacco product. It states that “leaf tobacco” must be identified based on type, variety, the cure method (including the heat source) and description of any recombinant DNA technology.

FDA Will Use Leaf Type

The FDA will use leaf type to determine future regulations and guidance materials. For example, if a certain of tobacco tends to show a higher level of a harmful constituent the FDA may use that information to promulgate a new standard or rule

Harmful Constituents

The Tobacco Product Center's Scientific Advisory Committee has appointed a Subcommittee to identify harmful and potentially harmful constituents in tobacco. It met this week. During the meeting the Subcommittee took a broad approach to the definition of harmful or potentially harmful. It included all constituents in the tobacco and smoke that are carcinogens, toxic at any level and cause addiction. The constituent list includes heavy metals and apparently other materials that are produced in the growing process. The Subcommittee made no distinction for materials that are unique to tobacco. Thus, even if the materials are a product of the soil and can be found in food items they were still included in the list. The list is approximately 106 items.

FDA Use of Constituent List

TPSAC will make a final recommendation to the FDA about the list of harmful constituents. The FDA staff has the authority to modify that list by selecting only some of the items or increasing it by adding new items. The question is what does FDA do with list once it is finalized. The FDA will require tobacco product manufacturers to test and provide the data to FDA on those constituents – the more items identified the more testing and the more information FDA will receive.

Growers/Warehouses Must Provide Information to Manufacturers

In addition, the definition of “tobacco warehouse” in the Act specifically requires them to provide to the manufacturer “all information” necessary for the manufacturer to comply with the Act including their reporting requirements. (Sec. 900(21)(a)). That information includes the type of tobacco and curing method which will be provided by growers. Again, even though the growers and warehouses are exempt under the Act they are still required to provide information to the manufacturers because they are required to provide it to the FDA.

FDA Terminology Is Confusing

- As noted, the Ingredients Guidance requires that “leaf tobacco” be identified based on “type”, “variety”, “the cure method” (including the source of the heat), and description of any “recombinant DNA technology.” The use of these terms in this context is confusing to members of the tobacco industry and should be clarified.
- In the tobacco industry, the “type” would convey a specific meaning such as flue-cured (interchangeable with Virginia), burley, dark fired and others, the basic curing method and plants from a specific group of varieties/cultivars. “Variety” on the other hand is viewed by the tobacco industry as the cultivar (i.e. variety name) used to produce the crop. In other words, the “type” of tobacco is produced using a certain variety of tobacco plants such as K326, NC 71, TN90, KY171, etc. Varieties and the heat source may vary from bale to bale depending on the grower usage and the tobacco mixed in the threshing process, while types and basic curing method, as defined by the industry, will not vary from bale to bale.

FDA May Adopt GMP's

The Act authorizes the FDA to prescribe regulations addressing “current good manufacturing process” for the manufacture, preproduction design validation, packing and storage of tobacco products. (Sec. 906(e)(1)(A)) As part of those regulations, the FDA “**may** provide for testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.” (Id.; emphasis added) Clearly, by using the word “may”, the Act does not make the imposition of testing on raw tobacco mandatory. Nonetheless, the imposition of chemical residue standards on tobacco products will impact warehouses and growers. The question is at what point the tobacco should be tested?

The Act Is Supposed to Minimize Impact to Growers

Requiring testing for pesticide chemical residue on the end tobacco products is consistent with the intent of the Act. The purpose of the Act is to regulate the manufacture and manufacturers of tobacco products. The FDA's authority over tobacco growers and tobacco warehouses is specifically limited by the Act itself. The Act specifically provides that it does not apply to "tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives..." (Sec. 901(c)(2)(A)) Clearly, Congress intended to minimize the Act's impact on these groups as they are "upstream" of the end products that certain companies import to and others manufacture within the U.S.

The Act May Not Govern Growers But It Will Impact Them

- Beginning two years after the effective date of the Act, manufacturers may not use tobacco, including foreign grown tobacco, which contains “pesticide chemical residue that is at a level greater than any specified by any tolerance applicable under Federal law to domestically grown tobacco.” (Sec. 907)
- Although the statute does not directly address domestic crops it does suggest that FDA may adopt CPA standards in the next year. That means that the FDA could dictate the amount and type of pesticides allowed to be on tobacco products. **The FDA will not tell growers what pesticides to use but will tell the product manufacturers who will tell their suppliers.**

FDA Regulations Can Dictate Grower Actions

The Act also specifies that any regulation establishing a tobacco product standard that in the FDA's determination "can only be met by manufacturers requiring substantial changes to the methods of farming" used by domestic farmers cannot take effect for at least two years after its adoption. (Sec. 907(d)(2)) The fact is that any regulation that impacts farming (not just those that are substantial) should not take effect for a sufficient period to allow the growers to comply.

Even If FDA Does Not Dictate to Growers the Manufactures Will

As noted above, the TPSAC meeting are using standards developed by the World Health Organization and Health Canada and others to develop standards for tobacco products. Simply because growers are exempt from the Act does not mean they will not be impacted. The imposition of standards for pesticides and levels of chemical components including naturally occurring materials means the farmer will be impacted at some point. If the manufacturer is required to use tobacco that has a certain level of heavy metals it means it will only buy tobacco that meets that criteria.

Technical Achievability Should Be Considered

The Act also provides that the FDA should consider the impact on domestic and international trade and whether “technical achievability” of compliance is possible within the time frames at issue. (Sec. 907(d)(2)) The FDA should consider that any changes to the process of growing tobacco must not take effect until the current planning and growing season is finished. Each proposed change and the amount of time needed before implementation should be carefully considered on a case by case basis but every change will need to allow the appropriate time for compliance.

TPSAC

The TPSAC is made up of mostly scientists that have worked in the anti-tobacco field. A few of them have been outspoken during the meetings about using the authority of the Act to restrict as much as possible the use of tobacco products. Several challenges have been made by tobacco product manufacturers about the objectivity of some of the members but the FDA has taken no action so far.

Menthol

The first recommendation that TPSAC will make regards menthol. It will issue a report by March of 2011 stating whether menthol as a characterizing flavor should be banned. TPSAC is required to use science to support its decision but the rhetoric at the meetings suggest that some of the members may be overlooking the science in order to reach a desired result.

Future TPSAC Decision

TPSAC is supposed to act as scientific body when it makes recommendations to the FDA. The FDA is required to ask TPSAC for guidance on regulations before they are adopted. TPSAC acting like a science based objective body is critical to having fair and reasonable regulations.

New Tobacco Products

The Act requires new tobacco products that are not shown to be substantially similar to products on the market on February 15, 2007, cannot be introduced without FDA approval. The development of this process and how it will impact growers remains to be seen. The standards and GMPs adopted by the FDA will require the industry to adapt.

Conclusion

Thank you for inviting me to here. It is important that you stay involved in the FDA activities because whether we like it or not they will impact all of us.