

# Tar, Nicotine and Other Smoke Constituent Disclosures

Federal Regulation of Tobacco: A Summary  
July 2009



## Background

On June 22, 2009, President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act, giving the U.S. Food and Drug Administration (FDA) comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products. The new law represents the most sweeping action taken to date to reduce what remains the leading preventable cause of death in the United States.

Before enactment of the new law, tobacco products were largely exempt from regulation under the nation's federal health and safety laws, including the Food, Drug, and Cosmetic Act. The FDA has regulated food, drugs and cosmetics for many decades, but not tobacco products, except in those rare circumstances when manufacturers made explicit health claims.

## What the New Law Does

The new law requires tobacco product manufacturers to disclose ingredients, including tar, nicotine and harmful smoke constituents, in their tobacco products. Effective six months after enactment of the law, tobacco companies will be required to disclose to the FDA the following information for each tobacco product brand and sub-brand:

- All ingredients added to the product or its tobacco, paper, filter or other part
- A description of the content, delivery and form of nicotine in each product
- A list of all constituents, including smoke constituents, identified by the FDA as harmful or potentially harmful to health
- All documents relating to the health, toxicological, behavioral or physiological effects of current or future tobacco products and their constituents, ingredients, components and additives

Manufacturers will also be required to inform the FDA of any changes to the contents of a given product, and to submit all such information at least 90 days prior to the introduction of new brands. The FDA, in turn, will be charged with publicly disseminating a brand-specific list of harmful and potentially harmful constituents.

The law further requires tobacco companies to provide, at the request of the agency, all documents relating to:

- Research on the health, harms or effects of tobacco products or any of their constituents or additives
- Whether the health risks of a tobacco product could be reduced by using a technology available or known to the tobacco company
- Tobacco product marketing research or the effectiveness of tobacco product marketing practices



Pursuant to regulations that the FDA will issue, the companies will be required to test and report on all tobacco product constituents, ingredients and additives, including smoke constituents, by brand and sub-brand, that the FDA determines should be tested to protect the public health.

Though not specifically set forth in the new FDA law, existing federal law will require tobacco companies, upon direction from the FDA, to turn over all documents identified above in electronic form, thus protecting the agency against inundation with potentially millions of pieces of paper.

The new law also amends the Federal Cigarette Labeling and Advertising Act (FCLAA) to require a rulemaking proceeding to determine whether cigarette and other tobacco product manufacturers should be required to disclose tar and nicotine levels on their advertising, packaging or labels. The FDA is authorized to establish new methods for measuring tar and nicotine levels. The same amendment allows the adoption of additional FCLAA-based rule-making that would require further disclosures to the public—but not on product labels or ads—relating to other tobacco product constituents if such disclosure were determined to increase consumer awareness of the health consequences of tobacco use or otherwise benefit public health.

The law also provides that states retain the power to require tobacco manufacturers to disclose ingredients and other information, including information currently exempt from disclosure under federal law, in the event states identify any information that has not already been obtained or shared by the FDA.

To learn more about FDA regulation of tobacco, visit [www.tclconline.org](http://www.tclconline.org).

The Tobacco Control Legal Consortium provides information and technical assistance on issues related to tobacco and public health, but does not provide legal representation or advice. This fact sheet should not be considered legal advice or a substitute for obtaining legal advice from an attorney who can represent you. If you have specific legal questions, we recommend that you consult with an attorney familiar with the laws of your jurisdiction.