

Tobacco Product Standards

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 Family Smoking Prevention and Tobacco Control Act adds a new Chapter IX to the Food, Drug, and Cosmetic Act, establishing and governing the regulation of tobacco products. A new Center for Tobacco Products is created within the FDA to establish tobacco product standards, which are regulations affecting the design or safety of a product. Chapter IX vests the FDA with jurisdiction to regulate both current and new tobacco products.

A fundamental feature of the new law is that it requires FDA review and approval of all new tobacco products before they can be introduced to the market. The agency will thus have the responsibility to regulate—or, if it deems appropriate, prohibit—novel or new products, including their marketing, sale and distribution. The agency may order changes in cigarettes and other existing tobacco products to meet new product standards. Such tobacco product standards are to be based on available medical, scientific and other technological evidence as appropriate for the protection of the public health. "Appropriate for the protection of the public health" is to be determined with respect to the risks and benefits to the population as a whole, including users and non-users of tobacco products, taking into account the increased or decreased likelihood that existing users of tobacco products will stop and that nonusers will start because of the new product standards.

The FDA is specifically authorized to prohibit adulterated or misbranded tobacco products, establish labeling requirements, and regulate manufacturing standards and modified risk tobacco products, thereby generally preempting previously existing state authority in those areas. Similarly, the law preempts states from separately licensing tobacco manufacturers and suppliers specifically and exclusively for tobacco product regulation purposes. The law also preserves, however, state and local governments' authority to implement fire-safe cigarette laws that regulate the ignition propensity of tobacco products.



The new law's product standard section directly prohibits any cigarettes with a characterizing flavor other than tobacco or menthol, but it does not mandate similar changes in other tobacco products. The FDA has the power to prohibit the use of flavors, including menthol, in all tobacco products.

The law does not allow the FDA to use its new product standard authority to reduce nicotine yields of a tobacco product to zero, but grants the FDA authority to determine whether nicotine can be reduced to levels that do not cause or sustain addiction, and, if so, to reduce nicotine yields to those levels.

The law does not allow the FDA to use its new product standard authority unilaterally to order a complete ban of tobacco products or of any specific type of existing tobacco product (i.e., the FDA could not ban all cigarettes, all small cigars, all big cigars, all smokeless tobacco products, all pipe tobacco or all roll-your-own tobacco), but authorizes the agency to ban any brand new type of tobacco product from being sold in the United States. The law also leaves untouched the power of Congress and the states to ban any tobacco products.

If the FDA determines that an additive or a constituent—in either the tobacco product or the smoke emitted by the product—is harmful and should be removed, the burden will be on a party challenging the proposed standard to prove that the proposed change will not reduce or eliminate the risk of illness or injury.

New Tobacco Products

The law places requirements and restrictions on new tobacco products that might be offered for sale in the United States. Before introducing any new tobacco product into the market, the law requires that the manufacturer disclose to the FDA information regarding the ingredients, constituents and nicotine level, as well as any documents relating to the health effects of the product or its ingredients and constituents (i.e., the same information manufacturers of all existing tobacco products must provide pursuant to the law). In addition, for any new tobacco product that is similar to existing tobacco products, the law requires that the manufacturer show the FDA that the product is substantially equivalent to a tobacco product already on the market and meets all related product standards for that type of product.

Before introducing any brand new tobacco product that is not similar to existing tobacco products, the law requires additional premarket review by the FDA based on the manufacturer's submission of, among other things, samples of the product and its proposed labeling; information on the tobacco product's ingredients, properties and principles of operation; available information on the health risks of the product; and information on how the product complies with existing tobacco product standards. Based on the goal of protecting overall public health, the FDA may permit the product to be sold, forbid its sale, or allow its sale subject to restrictions on its sale, distribution, and marketing.



Modified Risk Tobacco Products

Any tobacco products for which manufacturers make explicit health claims are subject to FDA authority under existing law, but the FDA has not applied this authority to reduced risk claims. The law does not change the FDA's authority in relation to tobacco products that are intended to be used for the treatment of tobacco dependence or for smoking cessation, or in relation to tobacco products claiming other health benefits separate from tobacco use risk reduction. But all tobacco products that manufacturers advertise or market, explicitly or implicitly, as offering a reduced risk of harm or disease compared to other tobacco products fall under the new provisions of the law relating to "modified risk tobacco products."

The law defines modified risk tobacco products as tobacco products sold or distributed to reduce harm or the risk of disease compared to other tobacco products, including, among other things, any product whose labeling or advertising explicitly or implicitly presents it as being less harmful than other commercially available tobacco products or having lower levels (or being free) of a specific substance.

Manufacturers will be required to obtain premarket approval before marketing or selling a modified risk tobacco product by providing the FDA with the information required of proposed brand new tobacco products, plus more extensive information on the product's effect on tobacco-related diseases and health and its ability to reduce risk. The law authorizes the FDA to approve a proposed modified risk tobacco product based on the submission of thoroughly substantiated information regarding the benefit of the product to overall public health.

For an approved product, the law requires the FDA to ensure that the advertising and labeling of such a product will enable the public to understand the modified risk characteristics of the product and its relative significance in relation to total health and all of the health harms associated with tobacco use. The FDA can also impose restrictions and requirements on the product's labeling and advertising and marketing to educate consumers or to protect public health.

Approval as a modified risk tobacco product will last for five years. The law requires manufacturers to conduct and annually report to the FDA post-market surveillance of such modified risk product's actual usage. If that surveillance, or any other evidence, shows that the availability of the product is not promoting overall public health gains, the FDA can rescind or not renew the approval.

Related Provisions

The law requires tobacco product manufacturers to disclose to the agency detailed information regarding ingredients, additives, nicotine, and harmful product and smoke constituents. This provides the FDA with information that it is authorized to use to order changes to tobacco products for purposes of reducing the harm they cause and to educate the public about the chemicals in tobacco products and health effects of tobacco use.



The law establishes a Tobacco Products Scientific Advisory Committee to help guide the FDA on the effects of alterations in the nicotine yields of tobacco products and on whether there exists a threshold level below which nicotine does not cause addiction in the case of a given tobacco product. The committee will also provide its review of “other safety, dependence, or health issues relating to tobacco products” when requested by the FDA. The committee will consist of 12 members and be heavily weighted toward public health. Voting members will include seven scientists or health professionals, one government official and one representative of the general public. Non-voting members, described by the law as serving in a “consulting” role, will include two representatives of the tobacco industry and one representative of tobacco growers. The law establishes additional protections against conflicts of interest—disallowing certain tobacco industry ties among voting members—and prohibits non-voting members from chairing the Advisory Committee.

Adulterated and Misbranded Tobacco Products

Adulterated and misbranded products are prohibited by the Food, Drug, and Cosmetic Act (FDCA). Most of the provisions in the FDA law are part of a new tobacco product section that has been added to the FDCA, including definitions of what constitutes prohibited adulterated and misbranded tobacco products. Under the amended statute, a tobacco product will be regarded as adulterated if, among other things, it is contaminated by any added poisonous or deleterious substance, its manufacturing facilities are not sanitary or fail to satisfy applicable product standards, or it does not have required premarket approval. The law further defines prohibited misbranded tobacco products to include, among other things, any tobacco product with packaging that fails to meet the specified packaging and labeling requirements or that was not manufactured in a facility duly registered under the Act. Ordinary cigarettes and other tobacco products are not considered adulterated or misbranded.

To learn more about FDA regulation of tobacco, visit 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.