



A Deeming Regulation: What is Possible Under the Law

This publication contains frequently asked questions regarding what a deeming regulation is, generally speaking, and what will happen once the U.S. Food and Drug Administration (FDA) issues a proposed regulation. For more information about what additional requirements the FDA proposes to include in a final regulation and how the public health community can participate in the process, see the resources on our [FDA Tobacco Action Center](#) webpage.

What is a Deeming Regulation?

The Family Smoking Prevention and Tobacco Control Act gives the FDA the authority to regulate tobacco products.¹ The Tobacco Control Act broadly defines “tobacco products” as any product that is “made or derived from tobacco” that is “intended for human consumption.”² However, the Act, when passed, only immediately applied to a few specific products: cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco.³ To regulate any other tobacco products, the Act requires the FDA to assert jurisdiction through regulation. In other words, for the FDA to start regulating cigars, e-cigarettes, hookah, and other products currently unregulated by the federal government, the FDA must create a rule through its formal notice-and-comment rulemaking process. A rule, or regulation, that extends the FDA’s jurisdiction to all tobacco products is often referred to as a Deeming Regulation because the language of the Tobacco Control Act states that the FDA can regulate additional tobacco products that it “deems to be subject” to the Act.⁴

What happens when the FDA implements a Deeming Regulation?

The Tobacco Control Act placed specific requirements and limits on tobacco products and the tobacco industry that took effect when the Act was passed. In addition, the Act delegates broad regulatory authority to the FDA to take additional steps, such as establishing product standards,⁵ and limiting the sale, distribution,⁶ advertising, and promotion of tobacco products.⁷ This existing legal framework can be divided into two categories: 1) those actions that relate to all products regulated by the FDA, which will apply automatically to deemed products and 2) those actions that relate to specific classes of products, which will not apply automatically to deemed products, and will only occur if the FDA takes steps in addition to asserting jurisdiction over those products.

Among the regulations that will automatically apply to newly regulated products are:

- Restrictions on adulterated products;⁸
- Prohibitions related to misbranded products;⁹
- Required disclosure of health information, including lists of ingredients by brand and sub-brand, description of nicotine delivery, and documentation of the health effects of each product;¹⁰
- Required registration of tobacco product manufacturers;¹¹
- Required disclosure of a list of all tobacco products including information related to labeling and advertising;¹²
- Premarket review of all products marketed after February 15, 2007;¹³
- Restrictions on making claims about modified risk;¹⁴ and
- Collection of user fees for cigars and pipe tobacco.¹⁵

These requirements in the Act will automatically apply when the FDA asserts jurisdiction over more tobacco products because the provisions of the Act containing these requirements use the term “tobacco products” when describing specific restrictions and requirements.

There are a number of provisions in the Tobacco Control Act that only apply to cigarettes and smokeless tobacco. Many of these provisions appeared in the FDA’s 1996 rule asserting jurisdiction over cigarettes and smokeless tobacco.¹⁶ While this rule was struck down by the U.S. Supreme Court in 2000,¹⁷ Congress modified and included most of the rule in the Tobacco Control Act in 2009.¹⁸ The chart below illustrates the provisions of the Act that only relate to cigarettes and smokeless tobacco.

Current Federal Restrictions on Cigarettes and Smokeless Tobacco

	Cigarettes	Smokeless Tobacco
Minimum age of 18 for purchase and age verification for those under 27	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Face-to-face sales only	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Minimum package size	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Prohibition on retailer opening packages	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Prohibition on sampling	<input checked="" type="checkbox"/>	Allowed in adult-only facilities
Prohibition on characterizing flavors	Menthol and tobacco flavors allowed	<input type="checkbox"/>
Mandatory warning labels	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Prohibition on brand name sponsorship of events	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Although these provisions do not automatically apply to “deemed” products, the FDA has the regulatory authority to extend these requirements to “deemed” products. For example, the FDA can prohibit characterizing flavors in all tobacco products through its authority to establish product standards. The FDA can also prohibit the sale of any tobacco products to persons under the age of eighteen through its authority to limit the sale and distribution of tobacco products.

It is also important to note that even with its broad authority, there are certain actions that the FDA cannot take. For example, the FDA cannot:

- Prohibit the use of tobacco products (e.g., establish smoke-free environments);
- Prohibit the sale of all cigarettes, smokeless tobacco, cigars, pipe tobacco, or roll-your-own tobacco;¹⁹
- Completely eliminate nicotine in tobacco products;²⁰
- Prohibit face-to-face sales of tobacco products in specific categories of retail outlets (e.g., prohibit products from being sold in pharmacies);²¹
- Require a prescription for tobacco products;²²
- Tax tobacco products;
- Raise the minimum purchase age of tobacco products beyond eighteen.²³

What steps will have to happen for the FDA to implement a Deeming Regulation?

The public health community has been anticipating a Deeming Regulation since the Tobacco Control Act was first passed. Since then, the FDA has repeatedly described the Deeming Regulation as a top priority for its regulation of tobacco products, and, between 2010 and 2014, announced several different deadlines for issuing a Deeming Regulation.²⁴ Despite those intentions and deadlines, none of the required next steps could begin until a Deeming Regulation was actually issued.

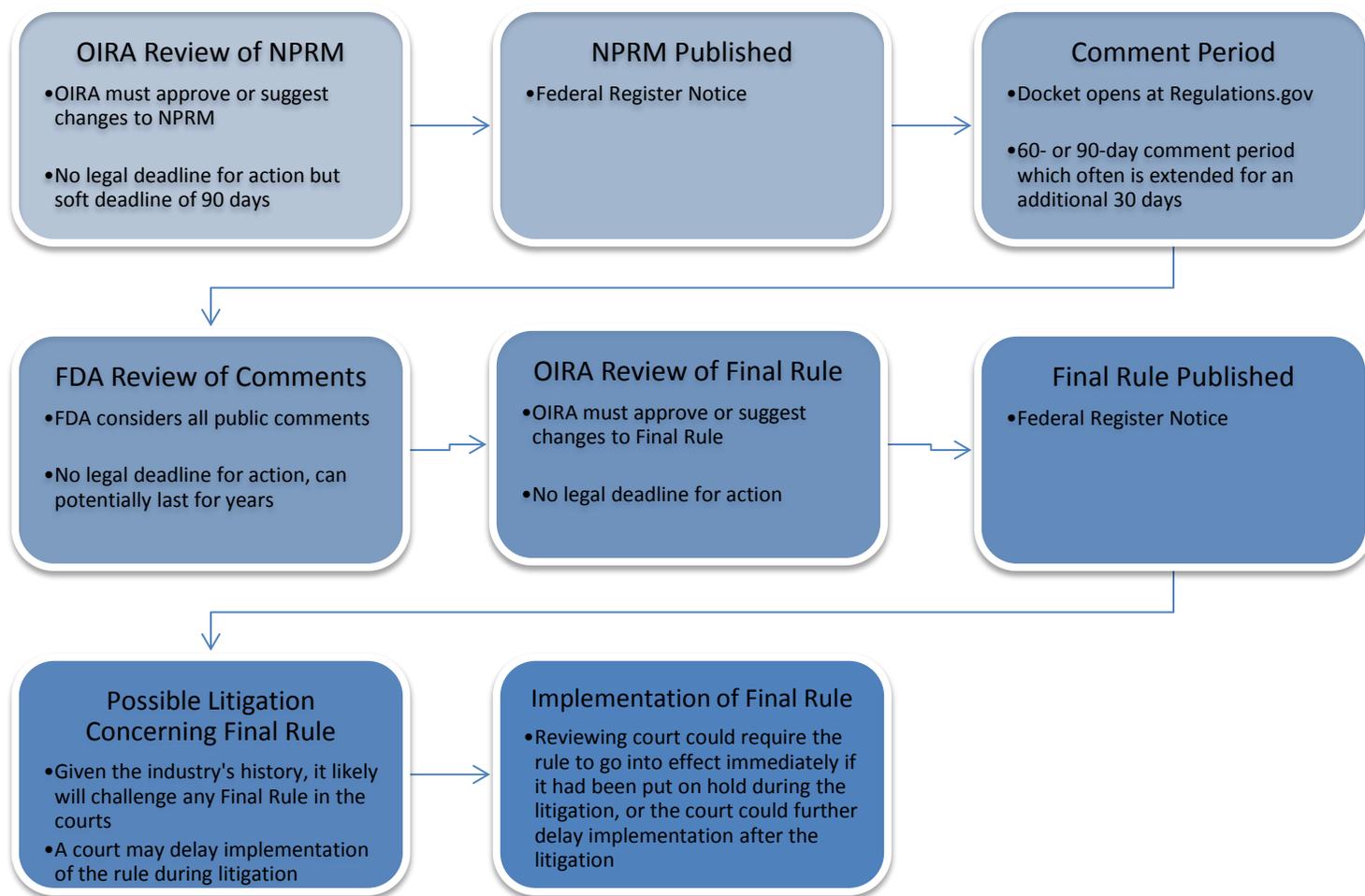
As explained above, the FDA must use its formal notice-and-comment rulemaking process to issue a Deeming Regulation. Although the process is relatively simple, there are several steps involved and many legal requirements that must be satisfied by the FDA. The notice-and-comment rulemaking process requires the FDA to publish a Notice of Proposed Rulemaking (NPRM) in the Federal Register that establishes the legal justification for, analyzes the impact of, and provides proposed language for the proposed rule.²⁵ The publication of the NPRM is only the first step in the process. The public then has an opportunity to provide comments to the agency on the NPRM for a period of time determined by the agency, which is often sixty days.²⁶ After the comment period expires, the FDA must read and consider all of the comments that it receives and then draft a final rule addressing the comments. The final rule is also published in the Federal Register, but the rule does not take effect immediately. Regulations with a particularly large scope like a Deeming Regulation often have a delayed effective date of twelve months or more following publication of the final rule. Because of the potentially large economic impact, there is a minimum sixty-day delay for the effective date of the Deeming Regulation.²⁷

In addition to the notice-and-comment process that allows for public input, there is also a process to allow the White House to provide feedback to the agency. Before the FDA could publish its NPRM for the Deeming Regulation, the text of the proposal had to be approved by the Office of Information and Regulatory Affairs (OIRA), a White House office that reviews significant

regulations for all executive branch agencies.²⁸ The FDA submitted the NPRM for the Deeming Regulation to OIRA on October 1, 2013. OIRA reviewed the NPRM for longer than the soft deadline of ninety days. OIRA must also review the FDA's final proposal before the FDA can publish a final rule in the Federal Register.

This graphic provides an overview of the steps required for the FDA to implement a Deeming Regulation.

The Deeming Regulation Process



Because few of the legal requirements have binding deadlines, there are many points in this process that could cause delays in getting the Deeming Regulation implemented. The FDA's review of comments is one potential source of large delays. The FDA still has three outstanding tobacco related NPRMs for which it has not yet issued final rules,²⁹ the oldest of which saw the comment period close on June 13, 2011.³⁰

Litigation can also have an impact on the timing of the implementation of a regulation or entirely prevent a rule from ever taking effect. It is difficult to speculate as to the effect that litigation might have on the timing of the Deeming Regulation. However, the final rule requiring large

graphic warnings on cigarette labels and advertising was published on June 22, 2011.³¹ The final appeal of that case, striking down the rule and preventing it from being implemented, was decided on August 24, 2012.³² Given the tobacco industry's past behavior,³³ it seems likely that the industry will challenge a Deeming Regulation in the courts, which could significantly delay or prevent the implementation of the rule.

Because of all of these uncertainties, it is impossible to accurately predict how long it would take for the Deeming Regulation to be implemented but even a quick and litigation-free process likely will take at least one year, at a minimum, from the publication of the NPRM to the implementation of the final rule.

Other Resources

For additional information on the Deeming Regulation, the Consortium has created two short videos, [Why Should I Care About a Deeming Regulation?](#), and [A Deeming Regulation: Expanding FDA Regulation of Tobacco Products](#). For information on specific FDA actions and ways in which you can participate, visit our [FDA Tobacco Action Center](#). For state and local governments interested in regulating other products, the Consortium has several publications that discuss the policy options for regulating [e-cigarettes](#) and [other tobacco products](#).

Last updated: April 2014

Notes

¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387) [hereinafter Tobacco Control Act].

² *Id.*

³ Tobacco Control Act, § 901(b), 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)).

⁴ The terms “rule” and “regulation” both refer to an administrative law that results from the rulemaking process. The terms are interchangeable. The term “deem” comes from: Tobacco Control Act, *supra* note 3.

⁵ Tobacco Control Act, § 907(a)(3), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)).

⁶ Tobacco Control Act, § 906(d), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)).

⁷ *Id.*

⁸ Tobacco Control Act, § 902, 123 Stat. at 1787-88 (codified at 21 U.S.C. § 387b).

⁹ Tobacco Control Act, § 903, 123 Stat. at 1788-90 (codified at 21 U.S.C. § 387c).

¹⁰ Tobacco Control Act, § 904, 123 Stat. at 1790-92 (codified at 21 U.S.C. § 387d).

¹¹ Tobacco Control Act, § 905(a)-(h), 123 Stat. at 1792-93 (codified at 21 U.S.C. § 387e(a)-(h)).

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- ¹² Tobacco Control Act, § 905(i), 123 Stat. at 1793-94 (codified at 21 U.S.C. § 387e(i)).
- ¹³ Tobacco Control Act, § 905(j), 123 Stat. at 1794-95 (codified at 21 U.S.C. § 387e(j)); Tobacco Control Act, § 910, 123 Stat. at 1807-12 (codified at 21 U.S.C. § 387j).
- ¹⁴ Tobacco Control Act, § 911, 123 Stat. at 1812-19 (codified at 21 U.S.C. § 387k).
- ¹⁵ Tobacco Control Act, § 919, 123 Stat. at 1826-30 (codified at 21 U.S.C. § 387s).
- ¹⁶ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 61 Fed. Reg. 168, 44398 (Aug. 28, 1996), *available at* <http://www.gpo.gov/fdsys/pkg/FR-1996-08-28/pdf/X96-10828.pdf>.
- ¹⁷ *U.S. Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).
- ¹⁸ Tobacco Control Act, § 102, 123 Stat. at 1830-33 (codified at 21 U.S.C. § 387a-1); 21 C.F.R. Part 1140.
- ¹⁹ Tobacco Control Act, § 907(d)(3)(A), 123 Stat. at 1803 (codified at 21 U.S.C. § 387g(d)(3)(A)).
- ²⁰ Tobacco Control Act, § 907(d)(3)(B), 123 Stat. at 1803 (codified at 21 U.S.C. § 387g(d)(3)(B)).
- ²¹ Tobacco Control Act, § 906(d)(3)(A)(i), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(3)(A)(i)).
- ²² Tobacco Control Act, § 906(d)(1), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(1)).
- ²³ Tobacco Control Act, § 906(d)(3)(A)(ii), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)(3)(A)(ii)).
- ²⁴ Regulatory Agenda, 75 Fed. Reg. 21,782 (April 26, 2010); Regulatory Agenda, 75 Fed. Reg. 79,764 (Dec. 20, 2010); Regulatory Agenda, 76 Fed. Reg. 40,052 (July 7, 2011); Regulatory Agenda, 77 Fed. Reg. 7,946 (Feb. 13, 2012); Regulatory Agenda, 78 Fed. Reg. 1,574 (Jan. 8, 2013); Regulatory Agenda, 78 Fed. Reg. 44,252 (July 23, 2013); Regulatory Agenda, 79 Fed. Reg. 1,158 (Jan. 7, 2014).
- ²⁵ 5 U.S.C. § 553(b).
- ²⁶ U.S. Food & Drug Admin., About FDA, Comment on Regulations, <http://www.fda.gov/aboutfda/contactfda/commentonregulations/default.htm>.
- ²⁷ 5 U.S.C. § 801(a)(B)(3).
- ²⁸ Executive Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993).
- ²⁹ FDA-2011-N-0121; FDA-2011-N-0493; FDA-2012-N-0920.
- ³⁰ FDA-2011-N-0493.
- ³¹ FDA-2010-N-0568.
- ³² *R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012).

³³ *United States v. Philip Morris USA, Inc.*, 449 F.Supp.2d 1 (D.D.C. 2006). For an overview of industry practices from the findings section of the case, see TOBACCO CONTROL LEGAL CONSORTIUM, *THE VERDICT IS IN: FINDINGS FROM UNITED STATES V. PHILIP MORRIS* (2006) available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>; see also Desmond Jenson, Tobacco Control Legal Consortium, *Racketeers at the Table: How the Tobacco Industry is Subverting the Public Health Purpose of Tobacco Regulation* (2013), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-synopsis-racketeers-table-2013.pdf>.