Altria
Altria Client Services

May 20, 2024

MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION
Packaging Material Exemption Request for Packaging Stewardship Program
Submitted by Altria Client Services LLC ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA"), John Middleton Co. ("JMC"), U.S. Smokeless Tobacco Company LLC ("USSTC"), NJOY, LLC ("NJOY"), and Helix Innovations LLC ("Helix")[1]

1. Which federal laws or regulations preclude or significantly diminish a producer's ability to increase the recyclability or reduce the volume of packaging material? Please provide specific citations and language.

We manufacture tobacco products which are distributed through our trade partners in Maine. The federal Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA") establishes a comprehensive framework of requirements that governs the manufacturing, marketing, and sale of tobacco products, which are further subject to the U.S. Food and Drug Administration's ("FDA") regulations. A "tobacco product" is defined as "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr)(1). Under the TCA, all tobacco product manufacturers must obtain FDA's premarket authorization before introducing a "new tobacco product" into interstate commerce. 21 U.S.C. § 387j(a)(1)-(2). In other words, a producer such as PM USA, JMC, USSTC, NJOY and Helix cannot market or sell a "new tobacco product" unless and until it has received FDA's approval.

Section 387b(6) of the TCA provides that tobacco products marketed without the appropriate authorization are considered "adulterated," which is expressly prohibited under federal law. *See* 21 U.S.C. § 331(a). The consequences of selling or offering for sale any "adulterated" tobacco products include being subject to a civil enforcement action by FDA, *id.* § 334, and even criminal penalties. *Id.* § 333. Therefore, to avoid violating federal law and being subject to these and other consequences, tobacco manufacturers must diligently abide by the premarket authorization process before introducing anything that is considered a "new tobacco product."

[1] PM USA, JMC, USSTC, NJOY, and Helix are wholly owned subsidiaries of Altria Group, Inc. ("Altria") that manufacture tobacco products sold in Maine. PM USA manufactures cigarettes in the United States, and JMC manufactures cigars and pipe tobacco. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products. NJOY manufactures and sells e-vapor products, and Helix manufactures oral tobacco-derived nicotine products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA, JMC, USSTC, NJOY, and Helix. Altria Group Distribution Company ("AGDC"), also a wholly owned subsidiary of Altria, manages the distribution of our tobacco products. There may be other such entities in the future that manufacture tobacco products subject to the TCA.

Under the TCA, "new" tobacco products are not limited to those that have not previously been sold before. A tobacco product is also "new" if it includes "*any modification* (including a change in design, *any component*, *any part*, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) *of a tobacco product*." *Id.* § 387j(a)(1)(B) (emphasis added); *see also* 21 C.F.R. § 1114.3 (defining "new tobacco product"). Accordingly, if a company makes any modification to a "component or part" of a tobacco product already being sold, the company must obtain a new premarket authorization from FDA.

One such modification that renders a tobacco product "new" and thus triggers the premarket review process is a change to the product's "container closure system." If a manufacturer seeks to modify packaging materials that are considered part of the container closure system, it must obtain pre-market authorization from FDA through one of the pre-market pathways ("substantial equivalence" or SE report, "premarket tobacco product application" or PMTA, and SE exemption) before making the change and marketing the product with the modified packaging. *See* 21 C.F.R. §§ 1107.1, 1107.18, 1114.7. Federal regulations define the "container closure system" of a tobacco product as "any packaging materials that are a *component or part* of a tobacco product." 21 C.F.R. § 1114.3; *see also* 86 Fed. Reg. at 55311 ("A container closure system [] is considered a component or part."). A "component or part" includes "materials intended or reasonably expected . . . [t]o alter or affect the tobacco product's performance, composition, constituents, or characteristics." 21 C.F.R. § 1114.3 (defining "component or part"). In turn, any packaging material that alters or affects the tobacco product's "performance, composition, constituents, or characteristics" is considered by FDA to be part of the tobacco product's container closure system.

FDA has provided examples of when tobacco product packaging materials may constitute part of a container closure system, including when "substances within that packaging are intended or reasonably expected to affect product moisture." 86 Fed. Reg. at 55311; *see also id.* ("[C]ompounds in packaging materials may diffuse into snuff and affect its characteristics. . . . Thus, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system."). Federal regulations further emphasize how FDA views these packaging materials as potentially affecting the tobacco product itself such as "potential leaching and migration of packaging constituents into the new tobacco product." *See* 21 C.F.R. § 1114.7(i)(1)(vi).

Based on these definitions, FDA has concluded that many types of packaging materials are a "component or part" of the tobacco product, and thus part of the container closure system that may not be modified without prior FDA authorization. The application for approval must include "information describing how the container closure system protects and preserves the product from damage during transport, environmental contaminants, and leaching and migration of constituents into the new tobacco product" while also "describing design features developed to prevent the risk of accidental exposure, if any (e.g., child-resistant packaging for e-liquids)." 86 Fed. Reg. at 55335. (Under the Child Nicotine Poisoning Prevention Act, 15 U.S.C. § 1472a, "any nicotine

provided in a liquid nicotine container" must utilize packaging that meets the requirements of 16 C.F.R. § 1700.15.)

For example, based on these definitions FDA has concluded that for cigarettes "each soft pack with surrounding cellophane is considered the container closure system." 86 Fed. Reg. at 55309-10. Likewise, FDA has made it clear that moist smokeless tobacco containers are container closure systems. FDA explained that switching between two container closure systems "(e.g., a plastic versus a metal container of smokeless tobacco)" will affect the moisture level and shelf life of a tobacco product, thus modifying a "component or part" of the tobacco product. *Id.* at 55311. Moreover, "chang[ing] the package of a moist snuff from plastic to fiberboard, which can affect microbial stability and tobacco-specific nitrosamine (TSNA) formation during storage," will affect the product's moisture and thus also amount to a modification to a "component or part" of the tobacco product. *Id.* Similarly, for cigars packaged in foil pouches or bags or "tubes" made of plastic, those packages would constitute the container closure system. As FDA has explained, in short, "modifications to . . . [any of these] container closure systems (e.g., change from glass to plastic e-liquid vials or from plastic to tin container closures) . . . *would result in a new tobacco product*" requiring premarket authorization. 86 Fed. Reg. at 55309 (emphasis added).

Obtaining premarket authorization is a significant undertaking entailing a lengthy process. Depending upon the type of tobacco product, the applicant must include in its application to the FDA various studies (e.g., stability studies, vapor transfer studies, etc.) demonstrating the performance of the packaging while in the market. Once the application is completed, it must then be accepted and approved by the FDA. Under FDA's current process for accepting and prioritizing premarket submissions for substantive review across an array of product categories, any marketing application filed today would be put at the end of a long line of already-pending applications that the FDA has yet to resolve and often takes years to resolve at its current pace. So while FDA reviews the application, new products cannot typically be marketed in the United States for at least 3 to 5 years, and perhaps even longer. *See* FDA, Tobacco Product Applications: Metrics & Reporting, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting.

For these reasons, under the federal regulatory framework for tobacco products, pursuing any modification to the design or material used for a tobacco product's packaging that qualifies as a container closure system can only happen after FDA's premarket authorization procedures are satisfied. This means that a tobacco product producer's "ability to increase the recyclability or reduce the volume of the packaging material" of its tobacco products is constrained, and indeed "significantly diminish[ed]," by federal law and regulations. *See* Section 13(D) of 38 M.R.S. § 2146. Therefore, ALCS respectfully requests that the Department exclude tobacco product packaging materials from its definition under the Packaging Stewardship Program.

2. If content or construction standards are not directly specified in the citations referenced in response to Question 1, please explain how the cited federal laws or regulations indirectly specify content or construction standards.

See above.

3. To which product or group of products do the federal laws or regulations referenced in response to Question 1 and any circumstances specified in response to Question 2 apply?

All "tobacco products," present and future, as defined in section 101(a) of the TCA. Any change to a tobacco product's packaging that constitutes the container closure system creates a "new tobacco product" that requires FDA premarket approval. 21 U.S.C. § 387j(a)(1)(B).

4. Do the federal laws or regulations referenced in response to Question 1 and any circumstances specified in response to Question 2 apply to some or all packaging material associated with the product or group of products identified in response to Question 3? If some, identify the packaging material that is affected.

The requirements under federal law and regulations apply to all packaging materials that constitute the "container closure system," as defined in 21 C.F.R. § 1114.3.

5. Who should the Department contact with questions regarding this exemption request?

Amanda J. Tate
amanda.j.tate@altria.com