

Consumer Product Safety Commission Gains New Authority Over Some Nicotine-Containing E-Liquid Packages

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With the passage of the Child Nicotine Poisoning Prevention Act ([S. 142](#)), the U.S. Consumer Product Safety Commission (CPSC) will soon get new authority to require child-resistant (CR) packaging (special packaging) over certain packages of nicotine-containing “e-liquid.” Effective 180 days from enactment of this Act—or from January 28, 2016, when the President signed the bill—covered products will be subject to the same requirements that CPSC already enforces on packaging of prescription drugs, some over-the-counter (OTC) drugs, and other potentially hazardous products found in the home.

Specifically, the law applies to “liquid nicotine containers,” defined to include “package[s] from which nicotine in a solution or other form is accessible through normal and foreseeable use by a consumer and that is used to hold soluble nicotine in any concentration.” Thus, bottles of refillable nicotine-containing e-liquid sold directly to consumers for use in “open-system” electronic vaping devices are covered, but packaging for zero-nicotine e-liquid—a growing segment of the e-liquid market—is not covered by the definition.

The new law also creates another important exception. Special packaging requirements would not apply to “sealed, pre-filled, and disposable” nicotine containers that are “inserted directly into an electronic cigarette, electronic nicotine delivery system, or other similar product,” so long as the nicotine is not accessible to consumers “through customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion or other contact by children.” In other words, “closed-system” electronic cigarettes (cigalikes) where the e-liquid is not intended to come into contact with or be handled by the consumer are not required to use CR packaging.

CPSC already implements the Poison Packaging Prevention Act of 1970 (PPPA), Pub. L. 91–601, 84 Stat. 1,670 (Dec. 30, 1970). That law requires certain household substances to have packaging that makes it significantly difficult for children under five years old to open within a reasonable amount of time. The PPPA is regarded as one of the CPSC’s biggest successes. For example, CPSC estimates a 45% reduction in deaths of children under 5 due to the unintentional ingestion of aspirin or oral prescriptions.

To meet PPPA requirements, 80% of children should not be able to open the special packaging after 10 minutes of attempting to open it. The CPSC has adopted [specifically prescribed testing](#).. Additionally, 90% of adults must be able to open the packages. A minimum of one panel of 50 children must be tested, along with 100 adults aged 50 to 70 years old. Manufacturers or importers of products that require special packaging must issue certificates of conformity indicating that their products comply with the special packaging requirements, and must issue/furnish them to distributors and retailers, and make them available to the CPSC or U.S. Customs and Border Protection (CBP) upon request, under provisions of the Consumer Product Safety Improvement Act (CPSIA).

The bill—formally [presented](#) to the President for his signature or veto on January 19, 2015—was originally introduced by Sen. Bill Nelson (D–FL) in summer 2014 in part because of the increase in Poison Control Center–reported incidents involving possible e-liquid ingestions, which can cause death or severe illness in large enough quantities. Indeed, in one case—although the facts are controversial, as apparently the consumer mixed e-liquid at home with very high concentrations of nicotine rather than using a commercially available product—one child death has been associated with access to an open bottle of e-liquid. Several states, including New York, Massachusetts, North Carolina, Texas, and Minnesota, have passed laws requiring CR packaging for e-liquid products.

Vaping advocates agree that CR packaging is necessary and note that most responsible manufacturers have been using such packaging for some time. The American E-Liquid Manufacturing Standards Association (AEMSA), a trade association of e-liquid manufacturers dedicated to the safe and responsible production and handling of these products, has required CR packaging for its members since 2012.

The new bill, which would take effect 180 days after it is signed into law, does not limit or pre-empt the Food and Drug Administration’s (FDA) authority to regulate e-cigarettes, and FDA would still be empowered to impose its own packaging requirements. Specifically, the Act mandates that FDA consult with the CPSC if the FDA “adopts, maintains, enforces, or imposes or continues in effect any packaging requirement for liquid nicotine containers, including a child-resistant packaging requirement ... taking into consideration the expertise of the Commission in implementing and enforcing this Act and the ... [PPPA].”

Electronic cigarettes and e-liquids that contain nicotine derived from tobacco fall within meaning of “tobacco product” under the Food, Drug and Cosmetic Act, as amended by the Family Smoking and Prevention and Tobacco Control Act (FSPTCA). While the FSPTCA only gave FDA the immediate regulatory authority over cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco products, it also gave FDA the authority to promulgate a regulation to “deem” other, currently unregulated tobacco products (including nicotine-containing e-cigarettes and e-liquid) to be regulated products subject to the FSPTCA. The so-called “Deeming Regulation” is currently in the final stages of review at the Office of Management and Budget (OMB) and is expected to be published in 2016.

Regardless of any new authority it obtains over e-cigarettes, as it has with certain drugs, it seems likely that FDA would defer to CPSC’s relatively successful approach to safeguarding children from ingesting easily openable dangerous products. Manufacturers and importers of liquid nicotine refill containers may want to begin reviewing the requirements of the law now in preparation for its implementation.

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