

Review of: "FDA-defined tobacco product"

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The definition itself remains valid, but the explanatory comment has been invalidated by the recent change of definition of a tobacco product in the US legislation. This change was made in order to define products using *synthetic* nicotine (i.e. nicotine not produced from tobacco leaf) as "tobacco products" so that these non-tobacco products would still fall under the jurisdiction of the Tobacco Control Act and the FDA as the regulator.

The change was introduced in The Consolidated Appropriations Act of 2022 [Pub. L. 117-103](#), enacted on March 15, 2022. The new definition of a tobacco product under the amended legislation is:

Tobacco product means 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 (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food (section 201(f)) if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

The amended definition is in [21 CFR § 1100.202 - Definitions](#) and applied from 20 March 2023.

The Federal Register entry describing the change is: *Definition of the Term "Tobacco Product" in Regulations Issued Under the Federal Food, Drug, and Cosmetic Act*, [88 FR 16551](#), 20 March 2023.

I think this further emphasises how inappropriate this terminology is for use in a scientific context. Tobacco products are a subset of nicotine products. Some nicotine products are made of tobacco (cigarettes, snus etc), and some are made from non-medicinal but pharmaceutical-grade nicotine liquids derived as extracts from tobacco leaf (typical e-liquids), and some have had no origin in a tobacco plant (synthetic nicotine). There is no reason to describe these all as "tobacco products" in a scientific, rather than legal, context. This applies inside the United States in any non-legal context. There is no reason to use this terminology outside the United States in *any* context.