
21 U.S. Code § 387k

Modified risk tobacco products

(a) In general

No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) Definitions

In this section:

(1) Modified risk tobacco product

The term “modified risk tobacco product” means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) Sold or distributed

(A) In general

With respect to a tobacco product, the term “sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products” means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors “light”, “mild”, or “low” or similar descriptors; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product’s label, labeling, or advertising, after June 22, 2009, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) Limitation

No tobacco product shall be considered to be “sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products”, except as described in subparagraph (A).

(C) Smokeless tobacco product

No smokeless tobacco product shall be considered to be “sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products” solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: “smokeless tobacco”, “smokeless tobacco product”, “not consumed by smoking”, “does not produce smoke”, “smokefree”, “smoke-free”, “without smoke”, “no smoke”, or “not smoke”.

(3) Effective date

The provisions of paragraph (2)(A)(ii) shall take effect 12 months after June 22, 2009, for those products whose label, labeling, or advertising contains the terms described in such paragraph on June 22, 2009. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with paragraph (2)(A)(ii).

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