438.305 Definitions for KRS 438.305 to 438.340. (Effective January 1, 2025)

As used in KRS 438.305 to 438.340, unless the context requires otherwise:

(1) (a) "Alternative nicotine product" means a noncombustible product containing nicotine that is intended for human consumption, whether chewed, absorbed, dissolved, or ingested by any other means.

(b) "Alternative nicotine product" does not include any product regulated as a drug or device by the United States Food and Drug Administration under Chapter V of the Food, Drug, and Cosmetic Act;

(2) "Authorized vapor product" means a vapor product containing nicotine for which the manufacturer has obtained:

(a) Authorization from the FDA; or

(b) A safe harbor certification;

(3) "Department" means the Department of Alcoholic Beverage Control;

(4) "FDA" means the United States Food and Drug Administration;

(5) "Manufacturer" means any person who manufactures or produces tobacco products within or without this Commonwealth;

(6) "Nonresident wholesaler" means any person who purchases cigarettes or other tobacco products directly from the manufacturer and maintains a permanent location or locations outside this state at which Kentucky cigarette tax evidence is attached or from which Kentucky cigarette tax is reported and paid;

(7) "Proof of age" means a driver's license or other documentary or written evidence of an individual's age;

(8) "Resident wholesaler" means any person who purchases at least seventy-five percent (75%) of all cigarettes or other tobacco products purchased by that person directly from the cigarette manufacturer on which the cigarette tax provided for in KRS 138.130 to 138.205 is unpaid, and who maintains an established place of business in this state at which the person attaches cigarette tax evidence or receives untaxed cigarettes;

(9) "Retailer" means any person, online or in person, who sells tobacco products, alternative nicotine products, or vapor products to a consumer for any purpose other than resale;

(10) "Safe harbor certification":

(a) Means a certification provided by a manufacturer establishing that a vapor product:

1. Falls within a safe harbor established by the FDA by the manufacturer's timely pursuing the path to market described in subparagraph 2. of this paragraph; and

2. Is a nicotine product containing tobacco-derived nicotine that was commercially marketed in the United States as of August 8, 2016, for which the manufacturer submitted a premarket tobacco product application on or before September 9, 2020, to the FDA that:

a. Remains under review, but has not received either a marketing

denial order or a marketing granted order;

b. Has received a marketing denial order, but remains under a stay by the FDA or continues to be subject to an appeal to or review by a court of competent jurisdiction; or

c. Has had a marketing denial order that has been rescinded by the FDA or vacated by a court of competent jurisdiction;

(b) Shall contain a copy of the first page of the communication from the FDA reflecting an acceptance for review or the submission tracking number or, if on appeal, a copy of the first page of the document filed with the applicable agency or court; and

(c) May be provided and maintained in hard copy or in electronic form;

(11) "Sample" means a tobacco product, alternative nicotine product, or vapor product distributed to members of the general public at no cost;

(12) "Subjobber" means any person who purchases tobacco products, on which the Kentucky cigarette tax has been paid, from a wholesaler licensed pursuant to KRS 138.195, and makes them available to a retail establishment for resale;

(13) "Tobacco noncompliance database and reporting system" means the database of retailers that have violated KRS 438.312 or 438.316 developed and maintained by the department under KRS 438.307;

(14) (a) "Tobacco product" means any cigarette, cigar, snuff, smokeless tobacco product, smoking tobacco, chewing tobacco, and any kind or form of tobacco prepared in a manner suitable for chewing or smoking, or both, or any kind or form of tobacco that is suitable to be placed in a person's mouth. "Tobacco product" also means any product made or derived from tobacco 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 any component, part, or accessory of a tobacco product, in accordance with the federal Tobacco Control Act, Pub. L. No. 111-31.

(b) "Tobacco product" does not include any alternative nicotine product, vapor product, or product regulated as a drug or device by the United States Food and Drug Administration under Chapter V of the Food, Drug, and Cosmetic Act;

(15) "Unauthorized vapor product":

(a) Means any vapor product that has not been authorized by the FDA; and

(b) Does not include a vapor product for which the manufacturer has received:

1. A marketing granted order or other authorization to market from the FDA; or

2. A safe harbor certification; and

(16) (a) "Vapor product" means any noncombustible product that employs a heating element, battery, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size and including the component parts and accessories thereto, that can be used to deliver vaporized nicotine or other substances to users inhaling from the device. "Vapor

product" includes but is not limited to any device deemed to be an electronic nicotine delivery system by the United States Food and Drug Administration, any electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device and every variation thereof, regardless of whether marketed as such, and any vapor cartridge or other container of a liquid solution or other material that is intended to be used with or in an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar product or device.

(b) "Vapor product" does not include any product regulated as a drug or device by the United States Food and Drug Administration under Chapter V of the Food, Drug, and Cosmetic Act.

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History: Amended 2024 Ky. Acts ch. 111, sec. 1, effective January 1, 2025. -- Amended 2020 Ky. Acts ch. 35, sec. 1, effective March 26, 2020. -- Amended 2014 Ky. Acts ch. 111, sec. 1, effective April 10, 2014. -- Amended 2000 Ky. Acts ch. 423, sec. 1, effective July 14, 2000. -- Amended 1996 Ky. Acts ch. 38, sec. 2, effective March 5, 1996. -- Created 1994 Ky. Acts ch. 480, sec. 2, effective July 15, 1994.