

SENATE BILL No. 395

DIGEST OF INTRODUCED BILL

Citations Affected: IC 7.1-7-4.

Synopsis: Regulation of e-liquid. Removes the requirement that the label on an e-liquid container must include a scannable code, including a quick response code, tied to a batch number.

Effective: July 1, 2016.

Mishler

January 12, 2016, read first time and referred to Committee on Public Policy.



Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

SENATE BILL No. 395

A BILL FOR AN ACT to amend the Indiana Code concerning alcohol and tobacco.

Be it enacted by the General Assembly of the State of Indiana:

- 1 SECTION 1. IC 7.1-7-4-1, AS AMENDED BY P.L.231-2015,
- 2 SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
- 3 JULY 1, 2016]: Sec. 1. (a) A manufacturer of e-liquid shall obtain a
- 4 permit from the commission before mixing, bottling, packaging, or
- 5 selling e-liquid to retailers or distributors in Indiana.
- 6 (b) The commission shall accept initial applications and issue
- 7 manufacturing permits until June 30, 2016.
- 8 (c) A manufacturing permit issued by the commission is valid for
- 9 five (5) years.
- 10 (d) An initial application for a manufacturing permit must include
- 11 the following:
- 12 (1) Plans for the construction and operation of the manufacturing
- 13 facility that demonstrate that the facility design is:
- 14 (A) designed to include a clean room space where all mixing
- 15 and bottling activities will occur; and
- 16 (B) capable of meeting all of the security requirements
- 17 contained in this article.



- 1 (2) A service agreement that:
 2 (A) the applicant has entered into with a security firm;
 3 (B) is valid for a period of five (5) years after the date of the
 4 permit application;
 5 (C) provides for the security firm to provide service and
 6 support to meet the security requirements established by this
 7 article;
 8 (D) requires the security firm to certify that the manufacturer
 9 meets all requirements set forth in ~~IC 7.1-7-4-6(10)~~ **section**
 10 **6(b)(9)** through ~~IC 7.1-7-4-6(15)~~; **6(b)(14) of this chapter**;
 11 (E) prohibits the security firm from withholding its
 12 certification as described in clause (D) because the security
 13 equipment of the applicant is not sold by or proprietary to the
 14 security firm; and
 15 (F) is renewable for the entire length of time that the applicant
 16 holds a permit issued by the commission.
- 17 (3) Verified documents satisfactory to the commission from the
 18 security firm demonstrating that the security firm meets the
 19 following requirements:
 20 (A) The security firm has continuously employed not less than
 21 one (1) employee for not less than the previous one (1) year
 22 period who is accredited or certified by both:
 23 (i) the Door and Hardware Institute as an Architectural
 24 Hardware Consultant; and
 25 (ii) the International Door Association as a certified Rolling
 26 Steel Fire Door Technician.
- 27 (B) The security firm has at least one (1) year of commercial
 28 experience, in the preceding year, with the following:
 29 (i) Video surveillance system design and installation with
 30 remote viewing capability from a secure facility.
 31 (ii) Owning and operating a security monitoring station with
 32 ownership control and use of a redundant offsite backup
 33 security monitoring station.
 34 (iii) Operating a facility that modifies commercial hollow
 35 metal doors, frames, and borrowed lights with authorization
 36 to apply the Underwriters Laboratories label.
- 37 (4) The name, telephone number, and address of the applicant.
 38 (5) The name, telephone number, and address of the
 39 manufacturing facility.
 40 (6) The projected output in liters per year of e-liquid of the
 41 manufacturing facility.
 42 (7) The name, telephone number, title, and address of the person



1 responsible for the manufacturing facility.

2 (8) Verification that the facility will comply with proper
3 manufacturing processes.

4 (9) Written consent allowing the state police department to
5 conduct a state or national criminal history background check on
6 any person listed on the application.

7 (10) Written consent allowing the commission, after a permit is
8 issued to the applicant, to enter during normal business hours the
9 premises where the e-liquid is manufactured to conduct physical
10 inspections, sample the product to ensure the e-liquid meets the
11 requirements for e-liquid set forth in this article, and perform an
12 audit.

13 (11) A nonrefundable initial application fee of one thousand
14 dollars (\$1,000).

15 (12) Any other information required by the commission for
16 purposes of administering this article.

17 SECTION 2. IC 7.1-7-4-2, AS ADDED BY P.L.176-2015,
18 SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
19 JULY 1, 2016]: Sec. 2. (a) A manufacturing permit that is renewed by
20 the commission is valid for five (5) years.

21 (b) A renewal application for a manufacturing permit must include
22 the following:

23 (1) The name, telephone number, and address of the applicant.

24 (2) The name, telephone number, and address of the
25 manufacturing facility.

26 (3) The annual output in liters of e-liquid of the manufacturing
27 facility for the five (5) years preceding the year of the application.

28 (4) The name, telephone number, title, and address of the person
29 responsible for the manufacturing facility.

30 (5) Certification by the applicant that the applicant will continue
31 to use the security protocol approved by the commission with the
32 applicant's initial application. However, if the applicant desires to
33 change the previously approved security protocol, the applicant
34 shall submit the suggested changes to the commission for
35 approval.

36 (6) Certification by the security firm with which the manufacturer
37 has a security agreement that the manufacturer meets all security
38 requirements set forth in section ~~6(10)~~ **6(b)(9)** through ~~6(15)~~
39 **6(b)(14)** of this chapter and that the security firm will not
40 withhold its certification because the security equipment of the
41 manufacturer is not sold by or proprietary to the security firm.

42 (7) Verification that the facility uses proper manufacturing



- 1 processes.
- 2 (8) Written consent allowing the state police department to
- 3 conduct a state or national criminal history background check on
- 4 any person listed on the application.
- 5 (9) Written consent allowing the commission, if a permit is
- 6 renewed to the applicant, to enter the premises where the e-liquid
- 7 is manufactured to conduct physical inspections, sample the
- 8 product to ensure the e-liquid meets the requirements of e-liquid
- 9 set forth in this article, and perform an audit.
- 10 (10) A nonrefundable renewal application fee of five hundred
- 11 dollars (\$500).
- 12 (11) Any other information required by the commission for
- 13 purposes of administering this article.
- 14 SECTION 3. IC 7.1-7-4-6, AS AMENDED BY P.L.231-2015,
- 15 SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
- 16 JULY 1, 2016]: Sec. 6. (a) As used in this section, "tamper evident
- 17 package" means a package having at least one (1) indicator or barrier
- 18 to entry that, if breached or missing, can reasonably be expected to
- 19 provide visible evidence to consumers that tampering has occurred.
- 20 (b) A manufacturing facility shall comply with the following
- 21 requirements:
- 22 (1) An e-liquid container must use a child proof cap that has the
- 23 child resistant effectiveness set forth in 16 CFR 1700.15(b)(1).
- 24 (2) An e-liquid container must use a tamper evident package. The
- 25 tamper evident package feature must be designed to and remain
- 26 intact when handled in a reasonable manner during the
- 27 manufacture, distribution, and retail display of the e-liquid
- 28 container.
- 29 (3) The label on an e-liquid container must identify the active
- 30 ingredients.
- 31 (4) The label must include a separate designation if the product
- 32 contains nicotine.
- 33 (5) The label or container must include a:
- 34 (A) batch number; and
- 35 (B) means for the commission to obtain the manufacturing
- 36 date.
- 37 ~~(6) The label must include a scannable code, including a quick~~
- 38 ~~response code, tied to the batch number as prescribed by the~~
- 39 ~~commission.~~
- 40 ~~(7) (6) An e-liquid container must be distributed by the~~
- 41 ~~manufacturer and sold by the manufacturer or the retailer by the~~
- 42 ~~earlier of either:~~



- 1 (A) the expiration or "best if used by" date; or
 2 (B) two (2) years of the date of manufacture.
- 3 ~~(8)~~ **(7)** The manufacturing facility must conduct all mixing and
 4 bottling activities in a clean room.
- 5 ~~(9)~~ **(8)** The manufacturer must take reasonable steps to ensure that
 6 an unauthorized ingredient is not included in any e-liquid
 7 produced for sale in Indiana.
- 8 ~~(10)~~ **(9)** The manufacturer must take reasonable steps to ensure
 9 that all ingredients used in the production of e-liquid are stored in
 10 a secure area accessible only by authorized personnel.
- 11 ~~(11)~~ **(10)** The manufacturer shall have a remotely monitored
 12 security system at the facility in areas where e-liquid is mixed,
 13 bottled, packaged, and stored.
- 14 ~~(12)~~ **(11)** The manufacturer shall have an exclusive high security
 15 key system that limits access to areas where e-liquid is mixed,
 16 bottled, packaged, and stored to authorized personnel only.
- 17 ~~(13)~~ **(12)** The manufacturer's facility must be subject to
 18 twenty-four (24) hour video recording where e-liquid is mixed,
 19 bottled, packaged, and stored. The video recordings must be
 20 retained for at least thirty (30) days.
- 21 ~~(14)~~ **(13)** The manufacturer must take reasonable steps to ensure
 22 that only authorized personnel have access to secured areas of the
 23 facility where e-liquid is mixed, bottled, and packaged.
- 24 ~~(15)~~ **(14)** The manufacturer must store and maintain three (3) ten
 25 (10) milliliter sample bottles from each production batch of more
 26 than two (2) liters for a period of not less than three (3) years in
 27 a secure, limited access area with recorded video surveillance.
- 28 ~~(16)~~ **(15)** The manufacturer must submit to random audits of the
 29 facility and the manufacturer's samples and records by the
 30 commission.
- 31 ~~(17)~~ **(16)** The manufacturer must submit to random site visits by
 32 the commission.
- 33 ~~(18)~~ **(17)** The manufacturer may:
 34 (A) own and control both the e-liquid manufacturing process
 35 and the bottling process; or
 36 (B) subcontract with another manufacturer for the performance
 37 of the e-liquid manufacturing service, the bottling services, or
 38 both services.
- 39 However, both the manufacturer performing a service under
 40 clause (B) and the manufacturer for which the service is
 41 performed must meet the requirements of this article.
- 42 ~~(19)~~ **(18)** The manufacturer or any person listed on the permit



1 application may not have been convicted of a felony or an offense
2 involving a controlled substance.

