

# SENATE BILL No. 1

DIGEST OF SB 1 (Updated February 22, 2017 4:14 pm - DI 107)

**Citations Affected:** IC 7.1-7; noncode.

Synopsis: E-liquids. Removes date restrictions in the e-liquids statutes. Removes the following requirements for an initial e-liquids manufacturing permit: (1) Construction and operation plans for manufacturing facilities. (2) Service agreements. (3) Security firm specifications. (4) Projected e-liquid production outputs. (5) Manufacturing process verifications. (6) Consent for the alcohol and tobacco commission (ATC) to conduct inspections. (7) Any other information required by the ATC. Requires a manufacturer to verify that it complies with manufacturing practices and ingredient listing requirements required by federal law. Removes the following renewal application requirements: (1) E-liquids production outputs. (2) Security certifications. (3) Consent for the ATC to conduct inspections. (4) Any other information required by the ATC. Requires a manufacturer to: (1) ensure that an e-liquid does not become adulterated; and (2) comply with registration requirements required by federal law. Removes language concerning security protocol confidentiality. Removes specific requirements concerning remotely monitored security systems. (Continued next page)

Effective: Upon passage.

Head, Alting, Boots, Holdman, Merritt, Doriot, Bohacek, Smith J, Walker, Becker, Charbonneau, Kruse, Raatz, Young M, Zay, Messmer, Lanane, Tomes, Mishler, Bassler, Ford

January 17, 2017, read first time and referred to Committee on Judiciary. February 23, 2017, amended, reported favorably — Do Pass.



## **Digest Continued**

Removes requirements regarding a manufacturer: (1) Keeping sample bottles from each batch of e-liquids produced. (2) Ensuring that e-liquid ingredients are stored in a secure area. (3) Ensuring that authorized personnel only have certain secured access. Provides that the ATC shall cover the cost of criminal history background checks. Removes e-liquid ingredient restrictions. Requires a manufacturer to submit a list of ingredients used in the manufacturer's e-liquid production to the ATC. Adds to the definition of "e-liquid" that an e-liquid is a substance that contains nicotine. Provides that an electronic cigarette uses a sealed nonrefillable cartridge containing not more than 5 milliliters of a liquid. Provides that a retailer who fails to verify the age of a person less than 27 years of age and sells the person e-liquids commits a Class C infraction. Provides that the federal Food and Drug Administration has sole jurisdiction to enforce a manufacturer to comply with certain federal laws. Provides that e-liquid manufacturer permit fees be deposited in the enforcement and administration fund of the alcohol and tobacco commission. Provides that e-liquids manufactured by an e-liquids manufacturer approved by the alcohol and tobacco commission prior to July 1, 2017, may be distributed and sold for retail until the expiration date of the e-liquids. Provides that rules relating to the manufacture, distribution, and sale of e-liquids are void.



### First Regular Session 120th General Assembly (2017)

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 2016 Regular Session of the General Assembly.

# **SENATE BILL No. 1**

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 7.1-7-1-2, AS ADDED BY P.L.176-2015,                   |
|---|--|
| 2 | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE                  |
| 3 | UPON PASSAGE]: Sec. 2. The purpose of this article is in the absence |
| 4 | of federal regulations, to protect public health and safety by:      |
| 5 | (1) ensuring the safety and security of e-liquid manufactured for    |
| 6 | sale in Indiana;   |
| 7 | (2) ensuring that e-liquid manufactured or sold in Indiana           |
| 8 | conforms to appropriate standards of identity, strength, quality,    |
| 9 | and purity; and  |
| 0 | (3) ensuring that e-liquid is not contaminated or adulterated by     |
| 1 | the inclusion of ingredients or other substances that might pose     |
| 2 | unreasonable threats to public health and safety.                    |
| 3 | SECTION 2. IC 7.1-7-2-3 IS REPEALED [EFFECTIVE UPON                  |
| 4 | PASSAGE]. Sec. 3. "Audit" means a procedure performed by the         |
| 5 | commission, including inspection of manufacturing facilities and     |



| 1   | $\underline{\text{preparation areas, review of required records, compliance checks, and}\\$ |
|-----|---|
| 2   | auditing of samples of e-liquid.  |
| 3   | SECTION 3. IC 7.1-7-2-4 IS REPEALED [EFFECTIVE UPON   |
| 4   | PASSAGE]. Sec. 4. "Clean room" refers to the part of an e-liquid                            |
| 5   | manufacturing facility where:   |
| 6   | (1) the mixing and bottling activities are conducted in secure and                          |
| 7   | sanitary conditions in a space that is kept in repair sufficient to                         |
| 8   | prevent e-liquid from becoming contaminated;  |
| 9   | (2) equipment used in the manufacturing process is easily                                   |
| 0   | cleanable, as defined in 410 IAC 7-24-27(a), in such a way that it                          |
| 1   | protects against contamination of e-liquid, e-liquid containers, or                         |
| 2   | e-liquid packaging materials; and   |
| 3   | (3) the cleaning and sanitizing of equipment is consistent with the                         |
| 4   | Indiana standards for public health and cleanliness that apply to                           |
| 5   | commercial kitchens in the state.   |
| 6   | SECTION 4. IC 7.1-7-2-6, AS ADDED BY P.L.176-2015,  |
| 7   | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE   |
| 8   | UPON PASSAGE]: Sec. 6. "Cooperative" means any group of people                              |
| 9   | who join together to manufacture e-liquids. The term does not mean                          |
| 20  | a member of a distribution chain or a component parts supplier.                             |
| 21  | SECTION 5. IC 7.1-7-2-9, AS ADDED BY P.L.176-2015,  |
| .2  | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE   |
| 22  | UPON PASSAGE]: Sec. 9. "Electronic cigarette" means a powered                               |
| 24  | vaporizer that:   |
| 2.5 | (1) is the size and shape of a traditional cigarette;                                       |
| 26  | (2) uses a sealed nonrefillable cartridge containing not more than                          |
| 27  | four (4) five (5) milliliters of a liquid; and  |
| 28  | (3) is intended to be vaporized and inhaled.  |
| .9  | The term does not include a vapor pen. product.   |
| 0   | SECTION 6. IC 7.1-7-2-10, AS ADDED BY P.L.176-2015,   |
| 1   | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE   |
| 2   | UPON PASSAGE]: Sec. 10. "E-liquid" means a substance that:                                  |
| 3   | (1) contains nicotine;  |
| 4   | (2) is intended to be vaporized and inhaled using a vapor pen;                              |
| 5   | product; and  |
| 6   | (2)(3) specifically excludes substances contained in nonrefillable                          |
| 7   | sealed cartridges of four (4) five (5) milliliters or less used in                          |
| 8   | electronic cigarettes.  |
| 9   | SECTION 7. IC 7.1-7-2-12 IS REPEALED [EFFECTIVE UPON  |
| 0   | PASSAGE]. Sec. 12: "Flavorings" means a food grade additive or                              |
| -1  | synthetic flavoring substance that is used to add flavor, that is approved                  |
| -2  | by the federal Food and Drug Administration as a permissible                                |



| 1  | flavoring, and that is not prohibited by law.  |
|--|--|
| 2  | SECTION 8. IC 7.1-7-2-13 IS REPEALED [EFFECTIVE UPON   |
| 3  | PASSAGE]. Sec. 13. "Key system" means a licensed or patented key   |
| 4  | design used to prevent unauthorized duplication of keys for use in high  |
| 5  | security installations, and that is prospectively exclusive to the security  |
| 6  | firm for a period of at least ten (10) years.  |
| 7  | SECTION 9. IC 7.1-7-2-14 IS REPEALED [EFFECTIVE UPON   |
| 8  | PASSAGE]. Sec. 14. "Locksmith" means a person who, or a firm that  |
| 9  | employs at least one (1) employee who, for the previous one (1) year   |
| 10   | period has been certified as a certified professional locksmith by the   |
| 11   | Associated Locksmiths of America.  |
| 12   | SECTION 10. IC 7.1-7-2-16, AS ADDED BY P.L.176-2015,   |
| 13   | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  |
| 14   | UPON PASSAGE]: Sec. 16. "Manufacturing" means the process by   |
| 15   | which an e-liquid is mixed, bottled, and packaged. and stored.   |
| 16   | SECTION 11. IC 7.1-7-2-20 IS REPEALED [EFFECTIVE UPON  |
| 17   | PASSAGE]. Sec. 20. "Quick response code" means a two (2)   |
| 18   | dimensional bar code that is used to provide easy access to information  |
| 19   | through a smartphone or other electronic mobile device.  |
| 20   | SECTION 12. IC 7.1-7-2-22 IS REPEALED [EFFECTIVE UPON  |
| 21   | PASSAGE]. Sec. 22. "Security firm" means an entity that:   |
| 22   | (1) is independent from an applicant and manufacturer;   |
|  | (1) is morp endend in our arrayment and manufacturer,  |
| 23   | (2) has experience in the security business; and   |
| 24   |  |
| 24<br>25   | (2) has experience in the security business; and   |
| 24<br>25<br>26   | (2) has experience in the security business; and (3) as of July 1, 2015:   |
| 24<br>25<br>26<br>27   | (2) has experience in the security business; and (3) as of July 1, 2015:  (A) meets the qualifications under IC 7.1-7-4-1(d)(3); (B) is a locksmith; and (C) provides services necessary to ensure the safety and  |
| 24<br>25<br>26<br>27<br>28   | (2) has experience in the security business; and (3) as of July 1, 2015:  (A) meets the qualifications under IC 7.1-7-4-1(d)(3); (B) is a locksmith; and   |
| 24<br>25<br>26<br>27<br>28<br>29   | (2) has experience in the security business; and (3) as of July 1, 2015:  (A) meets the qualifications under IC 7.1-7-4-1(d)(3); (B) is a locksmith; and (C) provides services necessary to ensure the safety and security of e-liquid manufactured for sale in Indiana.  SECTION 13. IC 7.1-7-2-23, AS ADDED BY P.L.176-2015,   |
| 24<br>25<br>26<br>27<br>28<br>29<br>30   | (2) has experience in the security business; and (3) as of July 1, 2015:  (A) meets the qualifications under IC 7.1-7-4-1(d)(3); (B) is a locksmith; and (C) provides services necessary to ensure the safety and security of e-liquid manufactured for sale in Indiana.  SECTION 13. IC 7.1-7-2-23, AS ADDED BY P.L.176-2015, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE   |
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| 24<br>25<br>26<br>27<br>28<br>29<br>30<br>31<br>32<br>33<br>34                                     | (2) has experience in the security business; and (3) as of July 1, 2015:  (A) meets the qualifications under IC 7.1-7-4-1(d)(3); (B) is a locksmith; and (C) provides services necessary to ensure the safety and security of e-liquid manufactured for sale in Indiana.  SECTION 13. IC 7.1-7-2-23, AS ADDED BY P.L.176-2015, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 23. "Vapor pen" product" means a powered vaporizer, other than an electronic cigarette, that converts e-liquid to   |
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| 24<br>25<br>26<br>27<br>28<br>29<br>30<br>31<br>32<br>33<br>34<br>35<br>36<br>37<br>38<br>39       | (2) has experience in the security business; and (3) as of July 1, 2015:  (A) meets the qualifications under IC 7.1-7-4-1(d)(3); (B) is a locksmith; and (C) provides services necessary to ensure the safety and security of e-liquid manufactured for sale in Indiana.  SECTION 13. IC 7.1-7-2-23, AS ADDED BY P.L.176-2015, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 23. "Vapor pen" product" means a powered vaporizer, other than an electronic cigarette, that converts e-liquid to a vapor intended for inhalation.  SECTION 14. IC 7.1-7-3-2, AS ADDED BY P.L.176-2015, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 2. (a) The commission has the following duties and responsibilities:  |
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| 24<br>25<br>26<br>27<br>28<br>29<br>30<br>31<br>32<br>33<br>34<br>35<br>36<br>37<br>38<br>39       | (2) has experience in the security business; and (3) as of July 1, 2015:  (A) meets the qualifications under IC 7.1-7-4-1(d)(3); (B) is a locksmith; and (C) provides services necessary to ensure the safety and security of e-liquid manufactured for sale in Indiana.  SECTION 13. IC 7.1-7-2-23, AS ADDED BY P.L.176-2015, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 23. "Vapor pen" product" means a powered vaporizer, other than an electronic cigarette, that converts e-liquid to a vapor intended for inhalation.  SECTION 14. IC 7.1-7-3-2, AS ADDED BY P.L.176-2015, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 2. (a) The commission has the following duties and responsibilities:  (1) To require the submission of information reports, plans, and specifications that are necessary to implement this article.                       |



| 1  | the commission.   |
|----|---|
| 2  | (4) To audit facilities that manufacture or sell e-liquid.              |
| 3  | (5) To audit random samples maintained by the manufacturer to           |
| 4  | ensure the safety and quality of the e-liquid and that the e-liquid     |
| 5  | meets the requirements in this article.                                 |
| 6  | (6) To ensure, in coordination with the department, that the            |
| 7  | e-liquid manufactured or sold in Indiana conforms to appropriate        |
| 8  | standards of identity, strength, quality, and purity.                   |
| 9  | (7) To approve not less than three (3) different independen             |
| 10 | testing laboratories to which a manufacturer may choose to send         |
| 11 | any e-liquid sample for testing, at the manufacturer's expense, a       |
| 12 | part of any audit, as directed by the commission.                       |
| 13 | (b) All records subject to audit by the commission under subsection     |
| 14 | (a) are declared confidential for the purposes of IC 5-14-3-4(a)(1) and |
| 15 | are not subject to inspection or copying by the public.                 |
| 16 | SECTION 15. IC 7.1-7-3-3 IS REPEALED [EFFECTIVE UPON                    |
| 17 | PASSAGE]. Sec. 3. (a) Not later than December 31, 2015, the             |
| 18 | commission shall adopt rules under IC 4-22-2, including emergency       |
| 19 | rules under IC 4-22-2-37.1, to implement this article.                  |
| 20 | (b) The commission shall adopt rules as described in subsection (a      |
| 21 | to establish minimum eligibility requirements for testing e-liquid      |
| 22 | under this article.   |
| 23 | SECTION 16. IC 7.1-7-4-1, AS AMENDED BY P.L.214-2016                    |
| 24 | SECTION 33, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE                    |
| 25 | UPON PASSAGE]: Sec. 1. (a) A manufacturer of e-liquid shall obtain      |
| 26 | a permit from the commission before mixing, bottling, packaging, o      |
| 27 | selling may not mix, bottle, package, or sell e-liquid to retailers     |
| 28 | consumers, or distributors in Indiana without a permit issued by the    |
| 29 | commission under this article.  |
| 30 | (b) The commission shall accept initial applications and issue          |
| 31 | manufacturing permits until June 30, 2016.                              |
| 32 | (b) All e-liquids manufactured by an e-liquids manufactured             |
| 33 | approved by the commission under IC 7.1-7-4 prior to July 1, 2017       |
| 34 | may be distributed and sold for retail until the expiration date o      |
| 35 | the e-liquids.  |
| 36 | (c) A manufacturing permit issued by the commission is valid fo         |
| 37 | five (5) years.   |
| 38 | (d) An initial application for a manufacturing permit must include      |
| 39 | the following:  |
| 40 | (1) Plans for the construction and operation of the manufacturing       |
| 41 | facility that demonstrate that the facility design is:                  |
|    | · · · · · · · · · · · · · · · · · · ·                                   |

(A) designed to include a clean room space where all mixing



| 1  | and bottling activities will occur; and                           |
|----|---|
| 2  | (B) capable of meeting all of the security requirements           |
| 3  | contained in this article.  |
| 4  | (2) A service agreement that:                                     |
| 5  | (A) the applicant has entered into with a security firm;          |
| 6  | (B) is valid for a period of five (5) years after the date of the |
| 7  | permit application;   |
| 8  | (C) provides for the security firm to provide service and         |
| 9  | support to meet the security requirements established by this     |
| 10 | article;  |
| 11 | (D) requires the security firm to certify that the manufacturer   |
| 12 | meets all requirements set forth in IC 7.1-7-4-6(10) through      |
| 13 | <del>IC 7.1-7-4-6(15);</del>                                      |
| 14 | (E) prohibits the security firm from withholding its              |
| 15 | certification as described in clause (D) because the security     |
| 16 | equipment of the applicant is not sold by or proprietary to the   |
| 17 | security firm; and  |
| 18 | (F) is renewable for the entire length of time that the applicant |
| 19 | holds a permit issued by the commission.                          |
| 20 | (3) Verified documents satisfactory to the commission from the    |
| 21 | security firm demonstrating that the security firm meets the      |
| 22 | following requirements:   |
| 23 | (A) The security firm has continuously employed for not less      |
| 24 | than the previous one (1) year period, both of the following:     |
| 25 | (i) At least one (1) employee who is accredited or certified      |
| 26 | by the Door and Hardware Institute as an Architectural            |
| 27 | Hardware Consultant.  |
| 28 | (ii) At least one (1) employee who is accredited or certified     |
| 29 | as a certified Rolling Steel Fire Door Technician by the          |
| 30 | International Door Association or the Institute of Door           |
| 31 | Dealer Education and Accreditation.                               |
| 32 | However, the security firm meets the requirements of this         |
| 33 | clause if the security firm continuously employed, for not less   |
| 34 | than the previous one (1) year period, one (1) employee who       |
| 35 | is accredited or certified under both item (i) and item (ii).     |
| 36 | (B) The security firm has at least one (1) year of commercial     |
| 37 | experience, in the preceding year, with the following:            |
| 38 | (i) Video surveillance system design and installation with        |
| 39 | remote viewing capability from a secure facility.                 |
| 40 | (ii) Owning and operating a security monitoring station with      |
| 41 | ownership control and use of a redundant offsite backup           |
| 42 | security monitoring station.                                      |



| 1  | (iii) Operating a facility that modifies commercial hollow          |
|----|---|
| 2  | metal doors, frames, and borrowed lights with authorization         |
| 3  | to apply the Underwriters Laboratories label.                       |
| 4  | (4) (1) The name, telephone number, and address of the applicant.   |
| 5  | (5) (2) The name, telephone number, and address of the              |
| 6  | manufacturing facility.   |
| 7  | (6) The projected output in liters per year of e-liquid of the      |
| 8  | manufacturing facility.   |
| 9  | (7) (3) The name, telephone number, title, and address of the       |
| 10 | person responsible for the manufacturing facility.                  |
| 11 | (8) (4) Verification that the facility will comply complies with    |
| 12 | proper manufacturing processes. applicable tobacco products         |
| 13 | good manufacturing practices promulgated under 21 U.S.C.            |
| 14 | 387f(e) of the federal Food, Drug, and Cosmetic Act.                |
| 15 | (5) Verification that the manufacturer has complied with the        |
| 16 | applicable ingredient listing required by 21 U.S.C. 387d(a)(1)      |
| 17 | of the federal Food, Drug, and Cosmetic Act.                        |
| 18 | (9) (6) Written consent allowing the state police department to     |
| 19 | conduct a state or national criminal history background check on    |
| 20 | any person listed on the application.                               |
| 21 | (10) Written consent allowing the commission, after a permit is     |
| 22 | issued to the applicant, to enter during normal business hours the  |
| 23 | premises where the e-liquid is manufactured to conduct physical     |
| 24 | inspections, sample the product to ensure the e-liquid meets the    |
| 25 | requirements for e-liquid set forth in this article, and perform an |
| 26 | <del>audit.</del>   |
| 27 | (11) (7) A nonrefundable initial application fee of one thousand    |
| 28 | dollars (\$1,000).  |
| 29 | (12) Any other information required by the commission for           |
| 30 | purposes of administering this article.                             |
| 31 | (e) The fees collected under subsection (d)(7) shall be deposited   |
| 32 | in the enforcement and administration fund established under        |
| 33 | IC 7.1-4-10.  |
| 34 | SECTION 17. IC 7.1-7-4-2, AS ADDED BY P.L.176-2015,                 |
| 35 | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE                 |
| 36 | UPON PASSAGE]: Sec. 2. (a) A manufacturing permit that is renewed   |
| 37 | by the commission is valid for five (5) years.                      |
| 38 | (b) A renewal application for a manufacturing permit must include   |
| 39 | the following:  |
| 40 | (1) The name, telephone number, and address of the applicant.       |
| 41 | (2) The name, telephone number, and address of the                  |
| 42 | manufacturing facility.   |



| 1  | (3) The annual output in liters of e-liquid of the manufacturing       |
|----|--|
| 2  | facility for the five (5) years preceding the year of the application. |
| 3  | (4) (3) The name, telephone number, title, and address of the          |
| 4  | person responsible for the manufacturing facility.                     |
| 5  | (5) Certification by the applicant that the applicant will continue    |
| 6  | to use the security protocol approved by the commission with the       |
| 7  | applicant's initial application. However, if the applicant desires to  |
| 8  | change the previously approved security protocol, the applicant        |
| 9  | shall submit the suggested changes to the commission for               |
| 10 | <del>approval.</del>   |
| 11 | (6) Certification by the security firm with which the manufacturer     |
| 12 | has a security agreement that the manufacturer meets all security      |
| 13 | requirements set forth in section 6(10) through 6(15) of this          |
| 14 | chapter and that the security firm will not withhold its               |
| 15 | certification because the security equipment of the manufactures       |
| 16 | is not sold by or proprietary to the security firm.                    |
| 17 | (7) (4) Verification that the facility uses proper manufacturing       |
| 18 | processes. complies with all tobacco products good                     |
| 19 | manufacturing practices:   |
| 20 | (A) set forth in; and  |
| 21 | (B) promulgated in federal rules under;                                |
| 22 | 21 U.S.C. 387f through 21 U.S.C. 387u of the federal Food              |
| 23 | Drug, and Cosmetic Act.  |
| 24 | (8) (5) Written consent allowing the state police department to        |
| 25 | conduct a state or national criminal history background check on       |
| 26 | any person listed on the application.                                  |
| 27 | (9) Written consent allowing the commission, if a permit is            |
| 28 | renewed to the applicant, to enter the premises where the e-liquid     |
| 29 | is manufactured to conduct physical inspections, sample the            |
| 30 | product to ensure the e-liquid meets the requirements of e-liquid      |
| 31 | set forth in this article, and perform an audit.                       |
| 32 | (10) (6) A nonrefundable renewal application fee of five hundred       |
| 33 | dollars (\$500).   |
| 34 | (11) Any other information required by the commission for              |
| 35 | purposes of administering this article.                                |
| 36 | (c) The fees collected under subsection (b)(6) shall be deposited      |
| 37 | in the enforcement and administration fund established under           |
| 38 | IC 7.1-4-10.   |
| 39 | SECTION 18. IC 7.1-7-4-3 IS REPEALED [EFFECTIVE UPON                   |
| 40 | PASSAGE]. Sec. 3. The security protocol that is employed at the        |
| 11 | applicant's facility is confidential under IC 5-14-2-4                 |

SECTION 19. IC 7.1-7-4-6, AS ADDED BY P.L.231-2015,



| 1              | SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE                  |
|----------------|---|
| 2              | UPON PASSAGE]: Sec. 6. (a) As used in this section, "tamper evident   |
| 3              | package" means a package having at least one (1) indicator or barrier |
| 4              | to entry that, if breached or missing, can reasonably be expected to  |
| 5              | provide visible evidence to consumers that tampering has occurred.    |
| 6              | (b) A manufacturing facility shall comply with the following          |
| 7              | requirements:   |
| 8              | (1) An e-liquid container must use a child proof cap that has the     |
| 9              | child resistant effectiveness set forth in the federal poison         |
| 0              | prevention packaging standards, 16 CFR 1700.15(b)(1).                 |
| 1              | (2) An e-liquid container must use a tamper evident package. The      |
| 2              | tamper evident package feature must be designed to and remain         |
| 3              | intact when handled in a reasonable manner during the                 |
| 4              | manufacture, distribution, and retail display of the e-liquid         |
| 5              | container.  |
| 6              | (3) The label on an e-liquid container must identify the active       |
| 7              | ingredients. meet the nicotine addictiveness warning statement        |
| 8              | requirements set forth in 21 CFR 1143.3.                              |
| 9              | (4) The label must include a separate designation if the product      |
| 20             | contains nicotine.  |
| 21             | (5) (4) The label or container must include a:                        |
| 22             | (A) batch number; lot code; and                                       |
| 22<br>23<br>24 | (B) means for the commission to obtain the manufacturing              |
| 24             | date.   |
| 25             | (6) The label must include a scannable code, including a quick        |
| 26             | response code, tied to the batch number as prescribed by the          |
| 27             | commission.   |
| 28             | (7) An e-liquid container must be distributed by the manufacturer     |
| 29             | and sold by the manufacturer or the retailer by the earlier of        |
| 0              | <del>either:</del>  |
| 1              | (A) the expiration or "best if used by" date; or                      |
| 2              | (B) two (2) years of the date of manufacture.                         |
| 3              | (8) The manufacturing facility must conduct all mixing and            |
| 4              | bottling activities in a clean room.                                  |
| 55             | (9) The manufacturer must take reasonable steps to ensure that an     |
| 6              | unauthorized ingredient is not included in any e-liquid produced      |
| 7              | for sale in Indiana.  |
| 8              | (5) The manufacturer must comply with all tobacco products            |
| 9              | good manufacturing practices:   |
| -0             | (A) set forth in; and   |
| -1             | (B) promulgated in federal rules under;                               |
| -2             | 21 U.S.C. 387f through 21 U.S.C. 387u of the federal Food,            |



| 1  | Drug, and Cosmetic Act.   |
|----|---|
| 2  | (6) The manufacturer shall take commercially reasonable             |
| 3  | steps to ensure that an e-liquid has not become adulterated a       |
| 4  | described in 21 U.S.C. 387b(1) through 21 U.S.C. 387b(3) o          |
| 5  | the federal Food, Drug, and Cosmetic Act.                           |
| 6  | (10) The manufacturer must take reasonable steps to ensure tha      |
| 7  | all ingredients used in the production of e-liquid are stored in    |
| 8  | secure area accessible only by authorized personnel.                |
| 9  | (11) The manufacturer shall have a remotely monitored security      |
| 10 | system at the facility. in areas where e-liquid is mixed, bottled   |
| 11 | <del>packaged, and stored.</del>                                    |
| 12 | (12) The manufacturer shall have an exclusive high security ke      |
| 13 | system that limits access to areas where e-liquid is mixed, bottled |
| 14 | packaged, and stored to authorized personnel only.                  |
| 15 | (13) The manufacturer's facility must be subject to twenty-fou      |
| 16 | (24) hour video recording where e-liquid is mixed, bottled          |
| 17 | packaged, and stored. The video recordings must be retained fo      |
| 18 | at least thirty (30) days.  |
| 19 | (14) The manufacturer must take reasonable steps to ensure tha      |
| 20 | only authorized personnel have access to secured areas of the       |
| 21 | facility where e-liquid is mixed, bottled, and packaged.            |
| 22 | (15) The manufacturer must store and maintain three (3) ten (10     |
| 23 | milliliter sample bottles from each production batch of more than   |
| 24 | two (2) liters for a period of not less than three (3) years in     |
| 25 | secure, limited access area with recorded video surveillance.       |
| 26 | (16) The manufacturer must submit to random audits of the           |
| 27 | facility and the manufacturer's samples and records by the          |
| 28 | commission.   |
| 29 | (17) The manufacturer must submit to random site visits by the      |
| 30 | commission.   |
| 31 | (7) A manufacturer must comply with the registration                |
| 32 | requirements required by 21 U.S.C. 387e(a) through (e) and          |
| 33 | 21 U.S.C. 387e(i) of the federal Food, Drug, and Cosmetic Act       |
| 34 | (18) (8) The manufacturer may:                                      |
| 35 | (A) own and control both the e-liquid manufacturing proces          |
| 36 | and the bottling process; or  |
| 37 | (B) subcontract with another manufacturer for the performance       |
| 38 | of the e-liquid manufacturing service, the bottling services, o     |
| 39 | both services.  |
| 40 | However, both the manufacturer performing a service unde            |
| 41 | clause (B) and the manufacturer for which the service i             |
| 42 | performed must meet the requirements of this article.               |



| 1  | (19) (9) The manufacturer or any person listed on the permit            |
|----|---|
| 2  | application may not have been convicted of a felony or an offense       |
| 3  | involving a controlled substance.                                       |
| 4  | SECTION 20. IC 7.1-7-4-7, AS ADDED BY P.L.176-2015,                     |
| 5  | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE                     |
| 6  | UPON PASSAGE]: Sec. 7. (a) On receipt of a completed permit             |
| 7  | application, the commission shall forward a copy of the application to  |
| 8  | the state police department.  |
| 9  | (b) The state police department shall perform a state or national       |
| 10 | criminal history background check of the applicant and return the       |
| 11 | application to the commission along with the state police department's  |
| 12 | findings from the state or national background check. The applicant is  |
| 13 | responsible for the cost of a state or national criminal history        |
| 14 | background check conducted under this article. The commission is        |
| 15 | responsible for the cost of a state or national criminal history        |
| 16 | background check.   |
| 17 | (b) (c) The commission shall review the permit application after it     |
| 18 | is returned from the state police department under subsection (a). (b). |
| 19 | The commission shall grant or deny a completed application for a        |
| 20 | permit within sixty (60) days of receipt of the application. If the     |
| 21 | commission determines that:   |
| 22 | (1) all the requirements under this article have been met; and          |
| 23 | (2) the applicant has not been convicted of a felony involving a        |
| 24 | controlled substance;   |
| 25 | the commission shall approve the application for issuance of the        |
| 26 | permit.   |
| 27 | (e) (d) If the completed application for a permit is denied, the        |
| 28 | commission must state the reasons for the denial. If a completed        |
| 29 | application is denied under this section, the applicant may reapply     |
| 30 | within thirty (30) days after the date of the denial. There is no       |
| 31 | application fee for a reapplication under this subsection.              |
| 32 | SECTION 21. IC 7.1-7-5-1, AS ADDED BY P.L.176-2015,                     |
| 33 | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE                     |
| 34 | UPON PASSAGE]: Sec. 1. (a) E-liquid distributed and sold within         |
| 35 | Indiana may be comprised of any of the following ingredients:           |
| 36 | (1) Vegetable glycerol or vegetable glycerin.                           |
| 37 | (2) Propylene glycol.   |
| 38 | (3) Nicotine.   |
| 39 | (4) Flavorings.   |
| 40 | (5) Water.  |

(6) Other ingredients approved by the department under section

2 of this chapter or any ingredient specifically approved for



| 1  | inclusion in e-liquid by the federal Food and Drug   |
|----|--|
| 2  | Administration.  |
| 3  | (b) A person may not purchase, sell, use, or possess any substance                               |
| 4  | intended to be vaporized and inhaled in a vapor pen that contains any                            |
| 5  | ingredient other than an ingredient allowed under subsection (a).                                |
| 6  | (c) All e-liquid retailers, distributors, and manufacturers who mix                              |
| 7  | bottle, or sell e-liquid in Indiana <del>before July 1, 2015,</del> shall <del>before July</del> |
| 8  | <del>1, 2016:</del>  |
| 9  | (1) sell or remove from retail all inventory of e-liquid   |
| 10 | manufactured before July 1, 2015, that was not manufactured                                      |
| 11 | mixed, bottled, packaged, stored, or sold in compliance with this                                |
| 12 | <del>article; or</del>   |
| 13 | (2) acquire:   |
| 14 | (A) (1) a valid tobacco sales certificate issued by the commission                               |
| 15 | in accordance with IC 7.1-3-18.5-1 that contains a separate box                                  |
| 16 | to check for identifying a retailer that sells e-liquids;  |
| 17 | (B) (2) an e-liquid manufacturing permit issued under IC 7.1-7-4                                 |
| 18 | or   |
| 19 | (C) (3) a distributor's license issued under IC 6-7-2-8.   |
| 20 | SECTION 22. IC 7.1-7-6-1, AS ADDED BY P.L.176-2015   |
| 21 | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  |
| 22 | UPON PASSAGE]: Sec. 1. (a) If a manufacturer violates this article                               |
| 23 | the manufacturer may be reprimanded, assessed a civil penalty, or have                           |
| 24 | the manufacturer's permit suspended. In the case of gross or willful                             |
| 25 | misconduct, the permit holder may have the manufacturer's permit                                 |
| 26 | suspended for a period of up to one (1) year. At the end of the                                  |
| 27 | suspension period, the manufacturer may apply to the commission for                              |
| 28 | reinstatement of the permit.   |
| 29 | (b) Any provision in this article that requires a manufacturer to                                |
| 30 | comply with the federal Food, Drug, and Cosmetic Act or a federal                                |
| 31 | rule promulgated under the federal Food, Drug, and Cosmetic Ac                                   |
| 32 | is under the sole jurisdiction of the federal Food and Drug                                      |
| 33 | Administration. If the federal Food and Drug Administration seeks                                |
| 34 | court enforcement of any section of the federal Food, Drug, and                                  |
| 35 | Cosmetic Act cited in this article and a civil monetary penalty is                               |
| 36 | assessed against the manufacturer, the penalty constitutes a                                     |
| 37 | violation of this article.   |
| 38 | (b) (c) The commission may assess a civil penalty against a                                      |
| 39 | manufacturer for a violation of this article in an amount that does no                           |
| 40 | exceed ten thousand dollars (\$10,000). A civil penalty may be assessed                          |
| 41 | in addition to other penalties allowed under this article.                                       |

SECTION 23. IC 7.1-7-6-2, AS ADDED BY P.L.176-2015,



| 1  | SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE                         |
|----|---|
| 2  | UPON PASSAGE]: Sec. 2. (a) If a retailer: knowingly sells e-liquid:         |
| 3  | (1) knowingly sells e-liquid to a minor; or                                 |
| 4  | (2) purchased from a manufacturer that does not have a permit; or           |
| 5  | (3) (2) that has been altered or tampered with; knowingly,                  |
| 6  | intentionally, or negligently fails to verify the age of a person           |
| 7  | who appears to be less than twenty-seven (27) years of age by               |
| 8  | checking a government issued identification and sells the                   |
| 9  | person e-liquid;  |
| 10 | the retailer commits a Class C infraction. For a sale to take place under   |
| 11 | this section, the buyer must pay the retail establishment for the e-liquid. |
| 12 | (b) Notwithstanding IC 34-28-5-4(c), a civil judgment for an                |
| 13 | infraction committed under this section must be imposed as follows:         |
| 14 | (1) If the retail establishment at that specific business location has      |
| 15 | not been issued a citation or summons for a violation of this               |
| 16 | section in the previous one hundred eighty (180) days, a civil              |
| 17 | penalty of up to two hundred dollars (\$200).                               |
| 18 | (2) If the retail establishment at that specific business location has      |
| 19 | had one (1) citation or summons issued for a violation of this              |
| 20 | section in the previous one hundred eighty (180) days, a civil              |
| 21 | penalty of up to four hundred dollars (\$400).                              |
| 22 | (3) If the retail establishment at that specific business location has      |
| 23 | had two (2) citations or summonses issued for a violation of this           |
| 24 | section in the previous one hundred eighty (180) days, a civil              |
| 25 | penalty of up to seven hundred dollars (\$700).                             |
| 26 | (4) If the retail establishment at that specific business location has      |
| 27 | had three (3) or more citations or summonses issued for a                   |
| 28 | violation of this section in the previous one hundred eighty (180)          |
| 29 | days, a civil penalty of up to one thousand dollars (\$1,000).              |
| 30 | A retail establishment may not be issued a citation or summons for a        |
| 31 | violation of this section more than once every twenty-four (24) hours       |
| 32 | for each specific business location.  |
| 33 | (c) It is not a defense that the person to whom e-liquid was sold or        |
| 34 | distributed did not inhale or otherwise consume e-liquid.                   |
| 35 | (d) The following defenses are available to a retail establishment          |
| 36 | accused of selling or distributing e-liquid to a person who is less than    |
| 37 | eighteen (18) years of age:   |
| 38 | (1) The buyer or recipient produced a driver's license bearing the          |
| 39 | purchaser's or recipient's photograph showing that the purchaser            |
| 40 | or recipient was of legal age to make the purchase.                         |
| 41 | (2) The buyer or recipient produced a photographic identification           |
| 42 | card issued under IC 9-24-16-1 or a similar card issued under the           |



| 1  | laws of another state or the federal government showing that the          |
|----|---|
| 2  | purchaser or recipient was of legal age to make the purchase.             |
| 3  | (3) The appearance of the purchaser or recipient was such that an         |
| 4  | ordinary prudent person would believe that the purchaser or               |
| 5  | recipient was not less than the age that complies with regulations        |
| 6  | promulgated by the federal Food and Drug Administration.                  |
| 7  | (e) It is a defense that the accused retail establishment sold or         |
| 8  | delivered e-liquid to a person who acted in the ordinary course of        |
| 9  | employment or a business concerning e-liquid:                             |
| 10 | (1) agriculture;  |
| 11 | (2) processing;   |
| 12 | (3) transporting;   |
| 13 | (4) wholesaling; or   |
| 14 | (5) retailing.  |
| 15 | (f) As used in this section, "distribute" means to give e-liquid to       |
| 16 | another person as a means of promoting, advertising, or marketing         |
| 17 | e-liquid to the general public.   |
| 18 | (g) Unless a person buys or receives e-liquid under the direction of      |
| 19 | a law enforcement officer as part of an enforcement action, a retail      |
| 20 | establishment that sells or distributes e-liquid is not liable for a      |
| 21 | violation of this section unless the person less than eighteen (18) years |
| 22 | of age who bought or received the e-liquid is issued a citation or        |
| 23 | summons in violation of this article.                                     |
| 24 | (h) Notwithstanding IC 34-28-5-5(c), civil penalties collected under      |
| 25 | this section must be deposited in the Richard D. Doyle youth tobacco      |
| 26 | education and enforcement fund (IC 7.1-6-2-6).                            |
| 27 | (i) A person who violates subsection (a) at least six (6) times in any    |
| 28 | one hundred eighty (180) day period commits habitual illegal sale of      |
| 29 | e-liquid, a Class B infraction.   |
| 30 | SECTION 24. IC 7.1-7-6-3 IS REPEALED [EFFECTIVE UPON                      |
| 31 | PASSAGE]. Sec. 3. (a) Except as otherwise permitted by this article,      |
| 32 | a person may not purchase, receive, manufacture, import, or transport,    |
| 33 | or cause to be imported or transported from another state, territory, or  |
| 34 | country into Indiana, or transport, ship, barter, give away, exchange,    |
| 35 | furnish, or otherwise handle or dispose of e-liquid, or to possess        |
| 36 | e-liquid for purpose of sale.   |
| 37 | (b) A person may not knowingly receive or acquire e-liquid from a         |
| 38 | person or authorized distributor who does not hold a valid permit under   |
| 39 | this article to sell, deliver, furnish, or give the e-liquid.             |
| 40 | (c) A person who violates this section commits a Class A infraction.      |
| 41 | SECTION 25. IC 7.1-7-6-4 IS REPEALED [EFFECTIVE UPON                      |

PASSAGE]. Sec. 4. (a) A permittee may bring a civil action against



| 1   | any:  |
|-----|---|
| 2   | (1) producer of e-liquid; or  |
| 3   | (2) other person or entity;   |
| 4   | that distributes an e-liquid not approved for sale in Indiana to a retailer |
| 5   | for the purposes of resale.   |
| 6   | (b) A permittee may bring the civil action described in subsection          |
| 7   | (a) in a court with jurisdiction in Indiana:                                |
| 8   | (1) based on a violation of this article or the rules adopted by the        |
| 9   | commission to enjoin the violation; and                                     |
| 10  | (2) to recover for actual monetary loss from the violation.                 |
| l 1 | The court shall award attorney's fees to the prevailing party.              |
| 12  | SECTION 26. [EFFECTIVE UPON PASSAGE] (a) 905 IAC 1-48                       |
| 13  | (Regulations Relating to Manufacture, Distribution, and Sale of             |
| 14  | E-liquids) is void. The publisher of the Indiana Administrative             |
| 15  | Code and Indiana Register shall remove this provision from the              |
| 16  | Indiana Administrative Code.  |
| 17  | (b) This SECTION expires July 1, 2018.                                      |
| 18  | SECTION 27. An emergency is declared for this act.                          |



### COMMITTEE REPORT

Madam President: The Senate Committee on Judiciary, to which was referred Senate Bill No. 1, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Replace the effective dates in SECTIONS 1 through 24 with "[EFFECTIVE UPON PASSAGE]".

Page 2, line 20, after "or" insert "a".

Page 4, delete lines 16 through 23, begin a new paragraph and insert:

"SECTION 15. IC 7.1-7-3-3 IS REPEALED [EFFECTIVE UPON PASSAGE]. Sec. 3. (a) Not later than December 31, 2015, the commission shall adopt rules under IC 4-22-2, including emergency rules under IC 4-22-2-37.1, to implement this article.

(b) The commission shall adopt rules as described in subsection (a) to establish minimum eligibility requirements for testing e-liquids under this article."

Page 4, line 28, after "retailers" insert ", consumers,".

Page 4, between lines 32 and 33, begin a new paragraph and insert:

"(b) All e-liquids manufactured by an e-liquids manufacturer approved by the commission under IC 7.1-7-4 prior to July 1, 2017, may be distributed and sold for retail until the expiration date of the e-liquids.".

Page 4, line 33, reset in roman "(c)".

Page 4, line 33, delete "(b)".

Page 4, line 35, reset in roman "(d)".

Page 4, line 35, delete "(c)".

Page 6, line 26, delete "(8)".

Page 6, line 26, strike "Any other information required by the commission for".

Page 6, strike line 27.

Page 6, between lines 27 and 28, begin a new paragraph and insert:

"(e) The fees collected under subsection (d)(7) shall be deposited in the enforcement and administration fund established under IC 7.1-4-10."

Page 7, line 11, strike "uses proper manufacturing".

Page 7, line 12, strike "processes." and insert "complies with all tobacco products good manufacturing practices:

(A) set forth in; and

(B) promulgated in federal rules under;

21 U.S.C. 387f through 21 U.S.C. 387u of the federal Food,



## Drug, and Cosmetic Act.".

Page 7, line 23, delete "(7)".

Page 7, line 23, strike "Any other information required by the commission for".

Page 7, strike line 24.

Page 7, between lines 24 and 25, begin a new paragraph and insert:

"(c) The fees collected under subsection (b)(6) shall be deposited in the enforcement and administration fund established under IC 7.1-4-10.".

Page 8, line 32, delete "required by" and insert "described in".

Page 8, line 32, delete "21 387b(3)" and insert "21 U.S.C. 387b(3)".

Page 8, line 34, delete "(7)".

Page 8, line 34, strike "The manufacturer must take reasonable steps to ensure".

Page 8, strike lines 35 through 36.

Page 8, line 37, delete "(8)".

Page 8, line 37, strike "The manufacturer shall have a remotely monitored".

Page 8, line 38, strike "security system at the facility.".

Page 9, line 5, delete "(9)".

Page 9, line 5, strike "The manufacturer must take reasonable steps to ensure".

Page 9, strike lines 6 through 7.

Page 9, line 17, delete "(10)" and insert "(7)".

Page 9, line 20, delete "(11)" and insert "(8)".

Page 9, line 29, delete "(12)" and insert "(9)".

Page 11, line 15, delete "requirement" and insert "provision".

Page 11, line 15, delete "a manufacturer must" and insert "requires a manufacturer to".

Page 11, line 18, delete "shall be" and insert "is under".

Page 11, line 21, delete "by" and insert "in".

Page 13, delete lines 16 through 27, begin a new paragraph and insert:

"SECTION 25. IC 7.1-7-6-3 IS REPEALED [EFFECTIVE UPON PASSAGE]. Sec. 3. (a) Except as otherwise permitted by this article, a person may not purchase, receive, manufacture, import, or transport, or cause to be imported or transported from another state, territory, or country into Indiana, or transport, ship, barter, give away, exchange, furnish, or otherwise handle or dispose of e-liquid, or to possess e-liquid for purpose of sale.

(b) A person may not knowingly receive or acquire e-liquid from a person or authorized distributor who does not hold a valid permit under



this article to sell, deliver, furnish, or give the e-liquid.

- (c) A person who violates this section commits a Class A infraction. SECTION 26. IC 7.1-7-6-4 IS REPEALED [EFFECTIVE UPON PASSAGE]. Sec. 4. (a) A permittee may bring a civil action against any:
  - (1) producer of e-liquid; or
  - (2) other person or entity;

that distributes an e-liquid not approved for sale in Indiana to a retailer for the purposes of resale.

- (b) A permittee may bring the civil action described in subsection (a) in a court with jurisdiction in Indiana:
  - (1) based on a violation of this article or the rules adopted by the commission to enjoin the violation; and
- (2) to recover for actual monetary loss from the violation.

The court shall award attorney's fees to the prevailing party.

SECTION 25. [EFFECTIVE UPON PASSAGE] (a) 905 IAC 1-48 (Regulations Relating to Manufacture, Distribution, and Sale of E-liquids) is void. The publisher of the Indiana Administrative Code and Indiana Register shall remove this provision from the Indiana Administrative Code.

(b) This SECTION expires July 1, 2018.

SECTION 26. An emergency is declared for this act.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 1 as introduced.)

BRAY, Chairperson

Committee Vote: Yeas 8, Nays 1.

