

STATE OF INDIANA)
) SS:
COUNTY OF MARION)

IN THE MARION CIRCUIT/SUPERIOR COURT
CAUSE NO. 49D04 15 12 PL 04 1749

HOOSIER VAPERS INC., an Indiana)
Non-profit Corporation, INDY VAPOR)
SHOP, LLC, an Indiana Limited Liability)
Corporation; JUST VAPOR, L.L.C., an)
Indiana Limited Liability Company;)
MELISSA ZOLLICOFFER d/b/a)
BIG WILLIE'S ELIQUIDS; GLASS)
CITY VAPORY, LLC, an Ohio Limited)
Liability Company; BOOSTED LLC)
d/b/a BOOSTED E-JUICE, a Colorado)
Limited Liability Corporation; and)
BRENT A. TAYLOR,)

Plaintiffs,)

vs.)

DAVID COOK, in his official capacity as)
Chairman of the Indiana Alcohol and)
Tobacco Commission; DAVID COLEMAN,)
in his official capacity as Vice Chairman of)
the Indiana Alcohol and Tobacco)
Commission; DALE GRUBB, in his)
official capacity as Commissioner of the)
Indiana Alcohol and Tobacco Commission;)
MARJORIE MAGINN, in her official)
capacity as Commissioner of the Indiana)
Alcohol and Tobacco Commission;)
MATT STRITTMATTER, in his official)
capacity as the Superintendent of the)
Indiana State Excise Police; and STATE OF)
INDIANA,)

Defendants.)

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Myla A. Eldridge
CLERK OF THE MARION CIRCUIT COURT

COMPLAINT AND MOTION FOR PRELIMINARY INJUNCTION

COMES NOW Plaintiffs, Hoosier Vapers, Inc., an Indiana non-profit corporation, Indy Vapor Shop, LLC, an Indiana Limited Liability Company, Just Vapor, L.L.C., an Indiana

Limited Liability Company, Melissa Zollicoffer d/b/a Big Willie's Eliquids of Indianapolis, Indiana, Glass City Vapory, LLC, an Ohio Limited Liability Company, Boosted, LLC, d/b/a/ Boosted E-Juice, a Colorado Limited Liability Company and Brent A. Taylor of Marion County, Indiana, by counsel and for their *Complaint and Motion for Preliminary Injunction* against Defendants David Cook, in his official capacity as Chairman of the Indiana Alcohol and Tobacco Commission; David Coleman, in his official capacity as Vice Chairman of the Indiana Alcohol and Tobacco Commission; Dale Grubb, in his official capacity as Commissioner of the Indiana Alcohol and Tobacco Commission; Marjorie Maginn, in her official capacity as Commissioner of the Indiana Alcohol and Tobacco Commission; Matt Strittmatter, in his official capacity as the Superintendent of the Indiana State Excise Police; and State of Indiana, allege and state as follows:

Plaintiffs

1. Plaintiff Hoosier Vapers, Inc. ("Hoosier") is an Indiana not-for-profit corporation with a principal place of business in Indianapolis, Marion County, Indiana. Hoosier's goals are to promote electronic vapor devices as a method of tobacco harm reduction to reduce smoking related death and disease. Hoosier advocates for reasonable and responsible laws and regulations for these devices and their ingredients, and to promote the interests of the industry and its consumers by engaging with governmental and other civic organizations. Its membership shares the same purposes and goals.
2. Plaintiff Indy Vapor Shop, LLC is a duly organized limited liability company under the laws of the State of Indiana with a principal place of business located in Indianapolis, Indiana. It is a retail operation that sells electronic vapor devices, e-liquid and other accessories to consumers.

3. Plaintiff Just Vapor, L.L.C. is a duly organized limited liability company under the laws of the State of Indiana with a principal place of business located in Fishers, Indiana. It is a retail operation that sells electronic vapor devices, e-liquid and other accessories to consumers.
4. Plaintiff Melissa Zollicoffer d/b/a Big Willie's Eliquids is an Indiana company with a principal place of business located in Indianapolis, Indiana. It is an e-liquid manufacturer.
5. Plaintiff Glass City Vapory, LLC is a duly organized limited liability company under the laws of the State of Ohio with a principal place of business located in Lancaster, Ohio. It is a retail operation that sells Indiana made e-liquid to consumers.
6. Plaintiff Boosted LLC d/b/a Boosted E-Juice is a duly organized limited liability company under the laws of the State of Colorado with a principal place of business located in Denver Colorado. It is an e-liquid manufacturer with its products distributed in Indiana, as well as in at least 40 states.
7. Plaintiff Brent A. Taylor ("Taylor") is a competent adult residing in Indianapolis, Marion County, Indiana. Taylor is a frequent user/consumer of vapor devices, e-liquid, and other accessories manufactured within and outside Indiana, and for himself.
8. Plaintiffs bring this action seeking, among other relief outlined below, to declare invalid and enjoin certain recently enacted statutory provisions, proposed regulatory rules and promulgated emergency regulatory rules as more fully described below because they violate the Indiana Constitution among other laws.
9. Plaintiffs' legal remedies are inadequate thereby causing them irreparable harm.

10. The ongoing and threatened injury to Plaintiffs outweighs the harm that Defendants will suffer should the Court grant the injunctive relief sought herein.
11. The public interest would not be disserved by granting the injunctive relief sought by Plaintiffs in the instant action.

State Defendants

12. Defendants David Cook and David Coleman are Chairman and Vice-Chairman, respectively, of the Indiana Alcohol and Tobacco Commission (“Commission”). Defendants Dale Grubb and Marjorie Maginn are Commissioners of the Commission. Defendant Matt Strittmatter is the Superintendent of the Indiana State Excise Police. Cook, Coleman, Grubb and Maginn are being sued in their respective official capacities. They are charged under Indiana law with the implementation and enforcement of the statutory provisions challenged herein and more specifically described below.
13. Defendant State of Indiana is a body politic. The State, acting through its legislature, enacted the challenged statutory provisions.
14. The foregoing Defendants (“State Defendants”) are acting, and have taken action, under color of state law with respect to the enactment, enforcement and/or supervision of the enforcement provisions of the challenged statutory provisions.

Statutory Enactment, Regulatory Enactment and Factual Background

15. Effective July 1, 2015, Indiana House Enrolled Act 1432 (“Public Law 176”) as modified in part by Indiana Senate Enrolled Act 463 defines and regulates, among other things, “e-liquid” (codified in I.C. §7.1-7-2-10).
16. Public Law 176 is having, and will have, a substantial impact on the electronic vapor industry in Indiana and across the country.

17. Both “electronic cigarettes” and “vapor pens,” as Public Law 176 defines such devices, are relatively new technologies that allow a consumer to simulate smoking a cigarette, cigar, or other combustible tobacco product without producing smoke, and the corresponding direct health hazards to such consumer, or the secondary or tertiary health hazards to third-parties who may find themselves in the proximity of a consumer.
18. Electronic cigarettes and vapor pens are battery-operated devices which cause the heating of metal coils contained therein when a consumer applies suction upon the device’s mouthpiece. The heating process causes the vaporization of a quantity of liquid contained in an enclosed storage tank. The result of this process is the exhaling of a quantity of vapor which is significantly safer and significantly less toxic than traditional combustible tobacco products, both to consumers and to any third-parties who may be in their proximity.
19. Electronic cigarettes and vapor pens are functionally equivalent devices based upon their purpose and utility.
20. The rise in popularity of electronic cigarettes and vapor pens has resulted in reduction in the consumption and use of traditional combustible tobacco products domestically and internationally.
21. Devices designed to be in the shape and size of traditional cigarettes and intended to be electronic cigarettes typically operate by means of a “closed” vaping system concept.
22. A device that utilizes an open vaping system would not be considered an “electronic cigarette” under Indiana law because it does not use a sealed nonrefillable cartridge.
23. A closed vaping system concept is characterized as utilizing sealed cartridges containing liquid which is not designed to be filled or re-filled by a consumer.
24. A vapor pen is not typically designed to be in the shape and size of traditional cigarettes

and is typically operated by means of an “open” vaping system concept.

25. An open vaping system concept is characterized as utilizing unsealed tanks which a user can fill and re-fill with a variety of different liquid.
26. Public Law 176 selectively regulates only one segment of the electronic vapor industry – the manufacture, distribution, and sale of e-liquid that are used in open vaping systems.
27. Public Law 176 imposes extensive regulations on open vaping systems, whereas it does not regulate disposable closed vaping systems.
28. Pursuant to I.C. §7.1-7-2-10, “E-liquid” means a substance that:
 - (1) is intended to be vaporized and inhaled using a vapor pen; and
 - (2) specifically excludes substances contained in nonrefillable sealed cartridges of four (4) milliliters or less used in electronic cigarettes.
29. Thus under Indiana law a substance is not considered e-liquid even if it is intended to be vaporized and inhaled using a vapor pen, so long as it is contained in a nonrefillable sealed cartridge of four (4) milliliters or less used in electronic cigarettes.
30. Pursuant to I.C. §7.1-7-2-23, “Vapor pen” means a powered vaporizer, other than an electronic cigarette, that converts e-liquid to a vapor intended for inhalation.
31. Pursuant to I.C. §7.1-7-2-9, “Electronic cigarette” means a powered vaporizer that:
 - (1) is the size and shape of a traditional cigarette;
 - (2) uses a sealed nonrefillable cartridge containing not more than four (4) milliliters of a liquid; and
 - (3) is intended to be vaporized and inhaledThe term does not include a vapor pen.
32. Thus under Indiana law e-liquid can be distinguished from “non-e-liquid” based on the size and shape of the vapor pen used in conjunction therewith, how e-liquid is contained within the vapor pen, and/or the extent to which the container or cartridge of e-liquid can be refilled.

33. Under Indiana law, an electronic cigarette does not contain e-liquid even if it contains the same ingredients as an e-liquid.
34. Public Law 176's stated purpose is: in the absence of federal regulation, to protect health and safety by ensuring the safety and security of e-liquid manufactured for sale in Indiana; ensuring that e-liquid manufactured or sold in Indiana conforms to appropriate standards of identity, strength, quality, and purity; and ensuring that e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health and safety.
35. Public Law 176 does not apply to any liquid, no matter how toxic, contained within an electronic cigarette.
36. Public Law 176 does not apply to any liquid, no matter how toxic, contained within a sealed nonrefillable cartridge containing not more than four (4) milliliters of any liquid.
37. Despite Public Law 176's stated purpose, it actually does not delve into ingredients but rather distinguishes based on the size and shape of the device containing the unregulated ingredients.
38. The liquid ingredients utilized in open vaping system devices (regulated by Public Law 176) and closed vaping system devices (not regulated by Public Law 176) are virtually identical in both their chemical composition and in their functional use.
39. Public Law 176 regulates activities up and down the e-liquid supply chain, including production, distribution, and retailing. Such pervasive regulations even affect out-of-state companies.
40. These regulations set forth obligations that reach far beyond any reasonable level of regulatory oversight and impose requirements that are unconstitutional under the Indiana

Constitution and unlawful under an existing Indiana statute in both their nature and scope.

41. I.C. §7.1-7-2-4 applies the Indiana commercial kitchen code to the production of e-liquid, even though e-liquid is not manufactured using food and is unlikely to become contaminated with a foodborne illness.
42. I.C. §7.1-7-4-1 requires that manufacturers of e-liquid hire an independent security firm that satisfies rigid certification and qualification standards where, upon information and belief, either no such firm exists or there are no firms that provide the geographical footprint necessary for all manufacturers to comply, or no such firm or firms exist that are willing to serve all manufacturers.
43. I. C. §7.1-7-4-6(b) grants authority to the State Defendants to conduct random audits of e-liquid production facilities across the United States.
44. E-liquid manufacturers, distributors, retailers, and consumers, like plaintiffs, have been forced to incur costs and expend resources as they make preparation to comply with Public Law 176 even though the U.S. Food and Drug Administration (“FDA”) is expected to issue a comprehensive rule in 2016 that regulates e-liquid and electronic vapor devices and, specifically, will apply FDA regulations to these products that guard against adulteration and contamination. While the final rule will likely preempt much of Public Law 176, the Indiana General Assembly chose not to defer to the FDA and, instead, subjects the electronic vapor industry to expensive and unattainable requirements that will eventually be rendered moot by federal action.
45. As a result, e-liquid manufacturers will have no choice but to abandon the Indiana market, distributors and retailers will no longer be able to sell those products, and Indiana consumers who use electronic vapor devices will ultimately bear the burden of not having

- the selection or quality of e-liquid products that are available in other states.
46. Pursuant to I.C. §7.1-7-3-3, the ATC “(n)ot later than December 31, 2015, . . . shall adopt rules under IC 4-22-2, including emergency rules under IC 4-22-2-37.1, to implement this article.”
 47. As of the filing of this Complaint only emergency rules have been issued by the Commission, which occurred on or about December 1, 2015. Additional regulations are apparently forthcoming.
 48. On September 9, 2015, the Indiana Register posted LSA Document #15-290, notifying of the Commission’s intention to adopt rules, via the addition of 905 IAC 1-48, establishing and implementing regulations for licensing the manufacture, distribution, and sale of e-liquid.
 49. Upon information and belief, a true and accurate copy of the most current proposed rules to be embodied within 905 IAC 1-48, as of the filing of this complaint, is attached hereto as Exhibit “1” (the “Regulations”).
 50. Upon information and belief, a true and accurate copy of the Commission’s Emergency Rule, promulgated on or about December 1, 2015, containing the Commission’s temporary rules to implement temporary regulations for licensing the manufacture, distribution, and sale of e-liquid, is attached hereto as Exhibit “2” (the “Emergency Rule”).
 51. 905 IAC 1-48-4 requires that “(a)nyone involved in manufacturing an e-liquid for sale to retailers or distributors in Indiana must first obtain an e-liquid manufacturer’s permit from the [Commission]” and that applications for the same must be submitted before June 30, 2016.
 52. Other aspects of the Regulations and Emergency Rule add further draconian measures to

the unconstitutional and unlawful aspects of Public Law 176.

COUNT I
VIOLATION OF INDIANA DUE PROCESS RIGHTS AND PRIVILEGES OR
IMMUNITIES CLAUSE

53. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
54. Article I, Section 23 of the Indiana Constitution prohibits the Indiana General Assembly from granting to one citizen or class of citizens any privilege or immunity which, upon the same terms, shall not belong to all citizens.
55. This has been interpreted by the Indiana Supreme Court to mean that the Indiana General Assembly shall not pass a statute that results in disparate treatment except where there are inherent characteristics distinguishing two classes.
56. This has further been interpreted by the Indiana Supreme Court to mean that the preferential treatment must be uniformly applicable to all who are similarly situated.
57. Because liquid intended for open and closed vaping systems are made of the same ingredients, and because some manufacturers actually sell the same liquid for use in open and closed vaping systems, all manufacturers are therefore indistinguishable and are comprised of a common class of citizens.
58. Article 1, Section 1 of the Indiana Constitution prohibits the Indiana General Assembly from creating a government beyond the scope of it being for the people's peace, safety and well-being.
59. Public Law 176, however, only regulates e-liquid used in open vaping systems, i.e. refillable devices.
60. Public Law 176 does not impose commercial kitchen or independent security firm obligations on liquid used in closed vaping systems (or "electronic cigarettes"), i.e. pre-

filled and non-refillable devices (I.C. §7.1-7-2-10).

61. Indiana draws this distinction despite the liquid used in both open and close vaping systems being the same.
62. Such liquid is made of identical ingredients (i.e. vegetable glycerin, propylene glycol, flavorings, and liquid nicotine).
63. As such, there is no material difference in the composition of liquid used in either type of system, closed or open.
64. Public law 176 fails to articulate a rationale for regulating only e-liquid used in open vaping systems.
65. Given that the liquid used in both types of systems contain the same ingredients, there is no evidence that liquid used in closed vaping systems are any less prone to bacteria or microorganisms that could lead to foodborne illness or are otherwise less likely to be contaminated.
66. To the extent that manufacturers of closed vaping systems make their own liquid, there is no evidence that they already comply with Indiana's commercial kitchen code and independent security firm measures.
67. To the extent there is any risk of adulteration, contamination, or sabotage, open and closed vaping systems are on equal footing.
68. Because there is no rational basis for regulating only e-liquid used in open vaping systems while granting immunity to similarly situated closed vaping systems, Public Law 176 violates Indiana's due process rights, Article 1, the privileges or immunities clause of Section 23 of the Indiana Constitution, and as it does nothing to ensure the people's peace, safety, and well-being it violates Article 1, Section 1 of the Indiana Constitution.

Therefore, the commercial kitchen, security, and audit requirements contained therein are invalid, should be declared unconstitutional and unlawful, and enforcement of the same should be enjoined.

COUNT II
VIOLATION OF INDIANA CONSTITUTION PRIVILEGES OR IMMUNITIES
CLAUSE

69. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
70. There exist no inherent characteristics that are material to distinguishing between open and closed vaping systems for purposes of protecting against the adulteration or contamination of e-liquid sold in Indiana.
71. Retailers and distributors selling e-liquid for vaping systems, whether in Indiana or over the internet, are also regulated only to the extent that they deal in e-liquid for open vaping systems.
72. Public Law 176 regulates e-liquid manufacturers both in Indiana and across the United States.
73. Public Law 176 defines “manufacturer” as “any person or cooperative, located inside or **outside** Indiana, that is engaged in manufacturing e-liquid” (I.C. §7.1-7-2-15) [emphasis added].
74. As part of the permitting process, Public Law 176 requires manufacturers to submit “[p]lans for the construction and operation of a facility” that meets various requirements (I.C. §7.1-7-4-1(d)(1)). Manufacturers must not only build a “clean room” that complies with Indiana’s commercial kitchen specifications (I.C. §7.1-7-2-4), but also hire an independent security firm with the proper certifications to install and operate a high level security system at the production facility (I.C. §7.1-7-4-1(d)).

75. To comply with the statute, these manufacturers will either have to retrofit their facilities to comply with the commercial kitchen code and the independent security firm/high level security requirements, or build an entirely new production facility to Indiana's specifications.
76. Under either scenario, however, Indiana seeks to directly regulate manufacturing activities taking place wholly outside the state.
77. Out-of-state manufacturers selling into Indiana will have no choice but to apply these standards to their entire production facility, which will necessarily cover products that are produced for sale in other states.
78. In other words, no manufacturer will build and operate two separate facilities – one dedicated to Indiana e-liquids and one committed to products sold in any of the other forty-nine states – with only an Indiana-related facility complying with the commercial kitchen and independent security firm/high level security requirements.
79. As a practical matter, products bound for other states will have to be produced under the same commercial kitchen and security regime as e-liquids heading for sale in Indiana.
80. Public Law 176 also results in extraterritorial regulation with regard to on-site audits.
81. Public Law 176 allows the Commission to conduct “random” on-site inspections of out-of-state manufacturers, including mixing and bottling areas and security systems. This means that Commission inspectors will necessarily be auditing manufacturing facilities and processes that are used to produce e-liquids for sale wholly outside Indiana, if Indiana had the authority to do so.
82. Indiana manufacturers are subject to the lawful authority in Indiana, but Indiana authorities have no jurisdiction or enforcement authority outside Indiana.

83. It will be difficult for Indiana authorities to enforce this aspect of Public Law 176.
84. Already this proscription has been challenged in federal court as unenforceable and prohibited by the Commerce Clause of the United States Constitution.
85. It will practically allow outside interests to skirt this inspection requirement of the statute while subjecting Indiana manufacturers to this requirement.
86. There will be disparate impact on the class of manufacturers, favoring out-of-state manufacturers over in-state manufacturers regarding facilities, inspections and audits required by Public Law 176.
87. Accordingly, Public Law 176 violates the Indiana Constitution and, thus, the commercial kitchen, security, and audit requirements should be declared invalid and unconstitutional, and enforcement of the same should be enjoined.

**COUNT III
VIOLATION OF INDIANA DUE PROCESS**

88. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
89. Public Law 176 defines “tobacco product” to include “e-liquid that contains tobacco.”
90. Indiana law does not define “tobacco.”
91. Because e-liquid is considered a tobacco product, distributors and retailers in Indiana and those selling e-liquid over the internet, must also obtain valid tobacco distributor licenses and sales certificates under Indiana’s general tobacco regulations.
92. Accordingly, Indiana is attempting to regulate e-liquid in the same manner as it controls the sale of traditional cigarette products.
93. E-liquid does not contain tobacco.
94. Nicotine is a naturally occurring chemical that exists separate and apart from the tobacco plant.

95. Nicotine can be synthesized in a laboratory and derived from non-tobacco plants.
96. Indeed, the FDA promotes the use of various smoking cessation products that contain nicotine, but does not regulate those as tobacco products under federal law.
97. Therefore, it is arbitrary and in violation of the due process clause to regulate e-liquid as tobacco products under Public Law 176.
98. Given that nicotine is not tobacco and that e-liquid does not contain tobacco, distributors and retailers will not be able to discern how Indiana defines “tobacco” under Public Law 176.
99. Indeed, other Indiana statutes appear to define “tobacco” to include only those products that traditionally have been understood to contain tobacco leaf or plant (*e.g.*, chewing tobacco, cigars, cigarettes, and pipe tobacco (I.C. §6-2.5-1-28)).
100. As a result, Indiana’s use of the word “tobacco” in Public Law 176 should be deemed void for vagueness.
101. Distributors and retailers will not reasonably know when their products will be considered as containing tobacco and therefore be subject to regulation under Indiana law.
102. Only those distributors and retailers who sell e-liquid for open vaping systems are subject to license and certification requirements, thereby violating both the Privileges or Immunities Clause of the Indiana Constitution and the due process rights afforded under Indiana law.
103. Public Law 176’s regulation of e-liquid as a “tobacco product” and the associated distributor and retailer requirements should, therefore, be declared unconstitutional and the enforcement of the same should be enjoined.

COUNT IV
VIOLATION OF PRIVILEGES OR IMMUNITIES CLAUSE OF THE INDIANA
CONSTITUTION

104. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
105. The general nature of Public Law 176 and Emergency Rule imposes tobacco and commercial kitchen regulation on a product which may or may not include nicotine, and with standards stricter than those on tobacco products and food.
106. There is no purpose to impose stricter standards on e-liquid than others in the industry of tobacco cigarettes, which by its treatment is what the Indiana General Assembly believes to be in the same class of retailer, manufacturers (insert rest).
107. Public Law 176's regulation of e-liquid as a "tobacco product" and the associated manufacturer, distributor and retailer requirements should, therefore, be declared unconstitutional and the enforcement of the same should be enjoined.

COUNT V
VIOLATION OF INDIANA DUE PROCESS AND INDIANA CONSTITUTION
PRIVILEGES OR IMMUNITIES CLAUSE

108. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
109. Article I, Section 23 of the Indiana Constitution prohibits the Indiana General Assembly from granting to one citizen or class of citizens any privilege or immunity which, upon the same terms, shall not belong to all citizens.
110. This has been interpreted by the Indiana Supreme Court to mean that the Indiana General Assembly shall not pass a statute that results in disparate treatment except where there are inherent characteristics distinguishing two classes.
111. This has further been interpreted by the Indiana Supreme Court to mean that the preferential treatment must be uniformly applicable to all who are similarly situated.

112. Not all e-liquid contain nicotine.
113. Public Law 176 and the Emergency Rule, as well as the Regulations, treats all e-liquid as if it contains nicotine.
114. Public Law 176 does not prohibit nicotine from being sold unless it is in the form of an e-liquid not produced by the permitting process within Public Law 176.
115. Nicotine is a naturally occurring product with many uses, including as natural insect repellent in pesticides.
116. Public Law 176 does not ban liquid nicotine solutions.
117. There is no rational basis for the distinction between liquid nicotine solutions, e-liquid which contains nicotine and e-liquid which contains no nicotine.
118. The disparate treatment on e-liquid is not based on inherent characteristics.
119. This violates both the Privileges or Immunities Clause of the Indiana Constitution and the due process rights afforded under Indiana law.
120. Public Law 176's regulation of e-liquid but not other nicotine products, and e-liquid that does not contain nicotine should, therefore, be declared unconstitutional, unlawful and the enforcement of the same should be enjoined.

COUNT VI
VIOLATION OF DUE REMEDY PROVISION OF THE INDIANA CONSTITUTION
AND I.C. §4-22-2-19.5

121. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
122. Due process traditionally requires that a law must have a rational relationship to a legitimate state interest.
123. A law whose chosen means do not bear a rational relationship to the asserted state interest is arbitrary and thus unconstitutional.

124. I.C. §4-22-2-19.5 codifies due process rights in administrative rule making.
125. I.C. §4-22-2-19.5 requires, to the extent possible, to minimize expenses incurred by regulated entities and consumers, and to achieve regulatory goals in the least restrictive manner.
126. I.C. §4-22-19.5 requires regulations to be written for ease of comprehension and practicable enforcement.
127. There are hundreds, if not thousands, of e-liquid manufacturers across the country, and for any of these companies who wish to do business in Indiana, they will be required to hire an independent security firm meeting the burdensome certification and high level security requirements set forth in Public Law 176, the requirements of the Emergency Rule, and proposed rules contained within, notifying of the Commission's intention to adopt rules. These manufacturers are not permitted to install and/or operate their own security systems.
128. Upon information and belief, there are no independent security firms in the United States who have met all of the certification provisions and other requirements laid out in the Regulations and Emergency Rule over the past year.
129. To provide e-liquid manufacturers with adequate security services, there will need to be qualifying firms in each locality where a manufacturer has a production facility so that the security firm may quickly and efficiently operate, maintain, and repair security equipment.
130. Because these types of firms and/or geographical coverage do not exist in the United States, it will be impossible for manufacturers to comply with the challenged security requirements.
131. There is no indication than an independent security firm with the requisite certifications and qualifications is needed to protect against any intentional tampering or sabotage – the

- only risks that the security requirements appear to address – that would result in an adulterated or contaminated e-liquid, or that manufacturers could not install and operate adequate security systems themselves.
132. Indeed, at least one certification – requiring a certified Rolling Steel Fire Door Technician – serves no purpose in protecting against adulteration and contamination.
 133. Imposing costly, if not unattainable, security requirements while depriving manufacturers of their right to install or manage their own security systems is completely arbitrary and lacks a foundation for the proposition that an independent security consultant delivers more efficacious security than a manufacturer who manages its own system.
 134. Retailers in Indiana or those marketing e-liquid over the internet will not be able to sell e-liquid that are not produced in compliance with the security provisions of Public Law 176, the Regulations and Emergency Rule.
 135. Accordingly, such retailers also suffer a constitutional injury where e-liquid manufacturers cannot comply with the security obligations set forth in Public Law 176.
 136. The independent security firm requirements of the Regulations and Emergency Rule, violate the due process provision of the Indiana Constitution.
 137. The challenged security firm requirements violate the requirements of I.C. §4-22-2-19.5 because they fail to minimize expenses, achieve regulatory goals in the least restrictive manner, fail to be written for ease of comprehension, do not have practicable enforcement, and it is possible to do so, therefore, such requirements should be declared unconstitutional and unlawful, and enforcement of same should be enjoined.

COUNT VIII
VIOLATION OF DUE REMEDY PROVISION OF THE INDIANA CONSTITUTION
AND I.C. §4-22-2-19.5

138. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
139. Due process traditionally requires that a law must have a rational relationship to a legitimate state interest.
140. A law whose chosen means do not bear a rational relationship to the asserted state interest is arbitrary and thus unconstitutional.
141. I.C. § 4-22-2-19.5 codifies due process characteristics in administrative rule making.
142. I.C. §4-22-2-19.5 requires, to the extent possible, to minimize expenses incurred by regulated entities and consumers, and to achieve regulatory goals in the least restricted manner.
143. I.C. §4-22-19.5 requires regulations to be written for ease of comprehension and practicable enforcement.
144. The Emergency Rule states in part:
- SECTION 1. (a) The purpose of this document is, in the absence of federal regulations, to protect public health and safety by:*
(1) ensuring the safety and security of e-liquid manufactured for sale in Indiana;
(2) ensuring that e-liquid manufactured or sold in Indiana conforms to appropriate standards of identity, strength, quality, and purity; and
(3) ensuring that e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health and safety. . . .
145. For the reasons stated herein, the Emergency Rule fails to do this in a manner the meets Indiana's due process requirements, as well as follows the stringent standards in I. C. §4-22-2-19.5.
146. Section 8(d) of the Emergency Rule requires a manufacturer to maintain a record of each

labeling of e-liquid containers identifying all ingredients.

147. "Ingredient" is ill-defined or not otherwise defined by statute or rule. Its common definitions are broad.
148. Compliance with Emergency Rule, Section 8(d) and Section 9(4) are not written to be comprehensive as required by I.C. §4-22-2-19.5 and it cannot be practicably enforced because "ingredient" is ill-defined and its meaning is not common as applied, and it cannot be enforced as what is to be enforced is unclear.
149. The cigarette industry and products for consumption or inhalation in Indiana are not required by state law to label their products with ingredients as comprehensively as e-liquid products.
150. Enforcement of Emergency Rule Section 8 (d) and Section 9 (4) will result in disparate treatment without there being there being inherent characteristics distinguishing between the above two classes.
151. All products for human consumption or inhalation are composed of myriads of chemical compounds. A strict interpretation of "ingredients" will result in voluminous product lists and determinations of "what is an ingredient", in which there is not generally accepted agreement.
152. The Emergency Rule's labeling requirements will cause manufacturers to hire or perform themselves, extensive and costly testing to determine every possible ingredient, an impossible task, to determine for itself "what is an ingredient".
153. Thus the requirements of the Emergency Rule are not understandable, are impossible to enforce, and are not the least costly or restrictive manner in which to regulate e-liquid.
154. The independent labeling and testing requirements of Emergency Rule, violate the due

process provision of the Indiana Constitution; therefore, such requirements should be declared void and unconstitutional, and enforcement of the same should be enjoined.

COUNT VIII

VIOLATION OF EMERGENCY RULE-MAKING AUTHORITY OF THE COMMISSION

155. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
156. The Commission is authorized by the Indiana General Assembly by Public Law 176 to engage in Emergency Rule making.
157. Emergency Rule Section 10 is beyond the authority vested in the Commission by the Indiana General Assembly.
158. Regarding the annual testing of products and their ingredients, Public Law 176 does not authorize the Commission to require e-liquid manufacturers to have their products tested annually by independent laboratories for any purpose.
159. Thus Section 10 of the Emergency Rule is illegal, unlawful and beyond the scope of the regulatory power and authority of the Commission.
160. Because there is no call, directly or indirectly, for such testing to implement Public Law 176 and thus no rational basis for Section 10 of the Emergency Rule in order to implement and enforce the statute, and furthermore as it fails to follow the rule-making standards of I.C. §4-22-2-19.5, Section 10 of the Emergency Rule is invalid, should be declared illegal, and contrary to statute and law, and enforcement of the same should be enjoined.

COUNT IX

VIOLATION OF INDIANA CONSTITUTION PRIVILEGE OR IMMUNITIES CLAUSE

161. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
162. Pursuant to Public Law 176, an individual person may not possess or use e-liquid unless manufactured by an Indiana permit holder, or make e-liquid for their personal use (I.C.

§7.1-7-6-3).

163. A person may possess tobacco cigarettes, beer and wine in Indiana manufactured in this state by any other person, manufactured in another state other than Indiana pursuant to that state's regulations, and may even manufacturer their own tobacco cigarettes, beer and wine for their own personal use, without sanction or penalty.
164. Public Law 176 is an attempt to regulate e-liquid generally as it does tobacco cigarettes, beer and wine except for possession of e-liquid made themselves for their own personal use or manufactured in another state pursuant to that state's laws.
165. Public Law 176 fails to provide adequate due process as it creates a system in which disparate treatment between the same class of citizens for behavior that the General Assembly generally finds to be the same in its nature, as well as regulations that mimic in many ways the regulations for tobacco products, beer and wine.
166. Because there is no guidance for degrees of rational basis for regulating personal manufacture, use and possession of out of state tobacco cigarettes, beer and wine Public Law 176 violates Article I, Section 23 of the Indiana Constitution, the provisions contained therein are invalid, should be declared unconstitutional, and enforcement of the same should be enjoined.

**COUNT X:
VIOLATION OF INDIANA CONSTITUTIONAL AND STATUTORY RIGHTS
CONCERNING INACTION OF ATC TO PROMULGATE COMPREHENSIVE
RULES AS DIRECTED BY THE GENERAL ASSEMBLY**

167. Public Law 176 directs the Commission to promulgate rules to implement its dictates. It directs ATC to do so on or before December 30, 2015.
168. The rules and procedures for promulgating regulatory rules by and agency are contained within I.C. §4-22-2 *et seq.*

169. The Commission has failed to promulgate rules as directed by Public Law 176.
170. The Commission instead promulgated Emergency Rules on December 1, 2015.
171. Public Law 176 directs the Commission to create application forms for the required license and to process the application forms. Application forms are due to the Commission on or before June 30, 2016.
172. The Commission has not promulgated rules other than the Emergency Rule and has not created applications for the permitting process, creating uncertainty as to any untimely and last minute rules close to the June 30, 2016 date for submitting applications for a permit.
173. The failure of the Commission to promulgate regulations and to create the permitting process, including applications, give uncertainty to the process and whether manufacturers seeking permits will be able to timely and effectively take action to meet the permitting requirements.
174. It also gives rise to the specter of manufacturers not being able to get a permit at all because of the dilatory practices of the Commission, which violates the dictates of the Indiana General Assembly and which makes its inaction unlawful. This inaction prejudices the plaintiffs, and injunctive relief is appropriate until a reasonable process and compliance timeframe is implemented.
175. This a violation of the manufacturers' due process rights under Indiana law and the Indiana Constitutional right to a due remedy by law of Article 1, Section 1.
176. The Commission's enforcement of the deadline of June 30, 2016 should be enjoined until and unless the application and permit process clearly allows sufficient time for interested parties to request, prepare and submit viable applications pursuant to Public Law 176 and the Commission's Emergency Rule and Regulations implementing it.

the Commission's Emergency Rule and Regulations implementing it.

COUNT XI

VIOLATION OF INDIANA CONSTITUTION PRIVILEGE OR IMMUNITIES CLAUSE

177. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
178. Public Law 176 prohibits any other person or entity that successfully applies for permits to obtain additional permits to expand or enhance their business operation after June 30, 2016.
179. There is no rational basis to limit additional permit holders or to limit permit holders the opportunity to expand their business after June 30, 2016 with additional permits.
180. Public Law 176 fails to provide adequate due process as it creates a system in which disparate treatment between the same class of citizens for behavior that has no distinguishing characteristics.
181. Because there is no rational basis for limiting the number of permit holders and for limiting the ability of permit holders to expand their businesses with additional or amended permits, Public Law 176 violates Article I, Section 23 of the Indiana Constitution, the provisions contained therein are invalid, should be declared unconstitutional, and enforcement of the same should be enjoined.

COUNT XII

VIOLATION OF INDIANA CONSTITUTION PRIVILEGE CLAUSE AND INHERENT RIGHTS CLAUSE

182. Plaintiffs incorporate herein by this reference each and every allegation set forth above.
183. Public Law 176 provides for penalties but no specifics for the application of the penalties. (I.C. §7.1-7-6 et seq.) The Commission has failed to promulgate rules and regulations regarding the penalties which may be applied pursuant to I.C. §7.1-7-6-1.
184. Civil penalties for manufacturers may include a reprimand, assessment of a civil penalty, or suspension of the manufacturer's permit for up to one year.

Assembly, this provision fails to provide due process and creates a system in which disparate treatment between two classes of citizens will become evident as the subjective nature of the penalties will create different levels of sanctions for similar or same violations.

186. These penalties, because of their lack of a rational application to similar events, violate the Indiana Constitution's Immunities or Privileges clause.
187. Because there is no guidance for degrees of imposing penalties pursuant to Public Law 176, such penalty provisions are invalid, should be declared unconstitutional, and the imposition of the same should be enjoined.

PRAYER FOR RELIEF

WHEREFORE, the above-captioned plaintiffs respectfully request the following relief to the extent not otherwise stated above:

- A. A declaration that the security requirements of Public Law 176 and any other challenged provisions herein violate the Indiana Constitution and are unconstitutional;
- B. A declaration that the commercial kitchen and audit requirements of Public Law 176 violate the Indiana Constitution and are unconstitutional;
- C. A preliminary and permanent injunction which restrains and enjoins the State Defendants from enforcing the challenged provisions of Public Law 176, the Regulations and the Emergency Rule;
- D. A preliminary injunction which stays the effective date of the challenged provision of Public Law 176 until any actions regarding preemption have been fully litigated and resolved;
- E. A preliminary and permanent injunction which restrains and enjoins the State Defendants

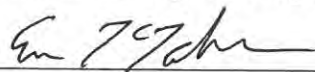
from enforcing a deadline of June 30, 2016 in which to file an application for a license to manufacture, distribute, and/or sell e-liquid;

- F. A preliminary and permanent injunction which restrains and enjoins the State Defendants from enforcing the prohibition against persons seeking to manufacture, distribute, and/or sell e-liquid that do not apply on or before June 30, 2016; and
- G. Any other relief that the Court deems appropriate in the premises.

VERIFICATION

I AFFIRM, UNDER THE PENALTIES FOR PERJURY, THAT TO THE BEST OF MY KNOWLEDGE AND BELIEF THE FOREGOING REPRESENTATIONS ARE TRUE.

Hoosier Vapers, Inc., an Indiana non-profit corporation

Signed: 

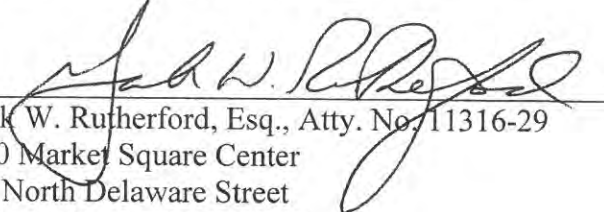
Printed: Evan McMahon

Title: Chairman

Respectfully submitted,

THRASHER BUSCHMANN & VOELKEL, P.C.
ATTORNEYS FOR PLAINTIFFS

By:



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TITLE 905 ALCOHOL AND TOBACCO COMMISSION

Proposed Rule
LSA Document

DIGEST

Adds 905 IAC 1-54 concerning the manufacture, distribution, and sale of e-liquid. Effective upon passage.

905 IAC 1-54

SECTION 1. 905 IAC 1-54 IS ADDED TO READ AS FOLLOWS:

Rule 54. Regulations relating to manufacture, distribution, and sale of e-liquids

905 IAC 1-54-1 Purpose and application

Authority:

Affected:

Sec. 1. (a) The purpose of this regulation is, in the absence of federal regulations, to protect public health and safety by:

- (1) Ensuring the safety and security of e-liquid manufactured for sale in Indiana;**
- (2) Ensuring that e-liquid manufactured or sold in Indiana conform to appropriate standards of identity, strength, quality, and purity; and**
- (3) Ensuring that e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health and safety.**

(b) This regulation applies to the commercial manufacturing, bottling, selling, bartering, or importing of e-liquid products in Indiana and the sale, possession, and use of e-liquid products in Indiana.

905 IAC 1-54-2 Sale to minors prohibited

Authority:

Affected:

Sec. 2. Any e-liquid or nicotine product, including non-refillable sealed cartridge electronic cigarettes, sold for use in Indiana may not be sold to anyone under the age of 18.

905 IAC 1-54-3 Definitions

Authority:

Affected:

Sec. 3. (a) All definitions set out in Indiana Code 7.1-7-9-2 are applicable to this regulation.

(b) "Packaging" means the process by which e-liquid is bottled in a tamper evident package with a child proof cap and labeled in compliance with Indiana Code Title 7.1-7. The term does not include the process of preparing to ship or distribute already manufactured and packaged e-liquid.

905 IAC 1-54-4 Manufacturer application

Authority:

Affected:

Sec. 4. (a) Anyone involved in manufacturing an e-liquid for sale to retailers or distributors in Indiana must first obtain an e-liquid manufacturer's permit from the Indiana Alcohol and Tobacco Commission



("ATC"). Initial applicants for an e-liquid manufacturer's permit must complete and submit the application prescribed by the ATC before June 30, 2016. Application will include the following:

- (1) Business name, mailing address and telephone number of the applicant;
- (2) Business name, telephone number and address of the manufacturing facility;
- (3) Full legal name, address, date of birth, social security number and primary telephone contact number for each owner;
- (4) Name, telephone number, date of birth, social security number, title, and address of the person(s) facility manager responsible for the manufacturing facility
- (5) Floor plans of the manufacturing facility that show the layout of the entire manufacturing facility including:
 - a. The clean room where all mixing and bottling activities occur;
 - b. The storage room where samples will be kept;
 - c. All entrances, exits, and interior doors;
 - d. All areas open to the public for sales or distribution.
- (6) An executed security agreement showing compliance with the requirements of IC 7.1-7-4-1 (d) (3) and IC 7.1-7-4-6(10) through 7.1-7-4-6 (15). Security agreement will be treated as confidential and only be released pursuant to a court order.
- (7) An addendum marked as confidential which includes the following:
 - (A) A listing by product name of all e-liquids that will be manufactured for the upcoming five (5) years from the date of the application;
 - (B) A listing of all the ingredients found in each product and the percentage of each ingredient. Ingredients shall be limited to the following:
 - (i) Vegetable glycerol or vegetable glycerin;
 - (ii) Propylene glycol;
 - (iii) Nicotine, not to exceed 18 milligrams per milliliter;
 - (iv) Flavorings - each type used; defined as a food grade additive or synthetic flavoring substance that is used to add flavor, that is approved by the federal Food and Drug Administration as Generally Recognized as Safe pursuant to 21 CFR 170.30(b) or 21 CFR 170.30(c), and that is not prohibited by law;
 - (v) Water; and
 - (vi) Other ingredients, listing each one separately and including an approval letter by the Indiana Department of Health for each of the other ingredients.
 - (C) Verification that the facility will comply with manufacturing processes required by IC 7.1-7 and this regulation;
 - (D) Confirmation that equipment used is easily cleanable as defined in 410 IAC 7-24-27 (a);
 - (E) In-state manufacturer owner(s) and manufacturer facility managers must submit to a State of Indiana fingerprint based background check through the Indiana State Police. The national background check must be submitted to the ATC before manufacturer's permit application can be approved. All fees for the background check shall be paid directly to the Indiana State Police.

Out of state applicants, are required to undergo similar national background check that can be performed by their state police or equivalent provider approved by Indiana ATC. All fees for background checks will be the responsibility of the applicant and paid directly to the background check provider.

A Indiana felony conviction or another state's equivalent to an Indiana felony conviction for a controlled substance offense operates as an automatic bar to the issuance of a permit under this section.

- (F) The submission and subsequent approval of an application under this section and for the life of the permit operates as consent for the Alcohol and Tobacco Commission or its duly appointed agents to enter the approved manufacturer premise during normal business hours to conduct physical inspections, product sampling for compliance with requirements of IC 7.1-7 or for the purposes of an audit;
- (G) Nonrefundable application fee of \$1,000; and
- (H) Any other information as deemed appropriate by the ATC to complete review of the application.

(b) The applicant is responsible for notifying the Indiana ATC within ten (10) business days if any information in the initial application changes. Failure to make a timely and accurate notification about information changes may result in the denial of the application.

905 IAC 1-54-5 Time allotted for review and action by the commission

Authority:

Affected:

Sec. 5. (a) ATC shall complete its review and take final action upon the application within sixty (60) days after receiving all required information and documentation. The application for e-liquid manufacturer will not be considered for final action until all of the following criteria are met;

- (1) The facility passes a final inspection by the ATC or its duly appointed agents ,
- (2) A fully compliant service security agreement is executed with final copy submitted to ATC,
- (3) All criminal backgrounds checks are final, and
- (4) Any other outstanding matters required by the ATC are satisfied.

(b) An approved manufacturer's permit will not be required for renewal until after five (5) years from the date of the either initial application's approval or the last renewal.

(c) For an out of state or out of country manufacturing facility that the ATC is unable to physically inspect, arrangements may be made for an independent provider approved by the Indiana ATC to perform such inspection. The out of state approved inspecting facility will be required to submit the results of the inspection directly to the Indiana ATC via first class mail.

(d) All costs associated with the inspection and reporting will be paid by the applicant.

905 IAC 1-54-6 Renewals

Authority:

Affected:

Sec. 6. (a) Applications for renewals of existing permits must be submitted to the ATC on an application form prescribed by the ATC no less than 60 days preceding the expiration date of the existing permit and must include the following;

- (1) The full legal name, social security number date of birth and address of the owner(s).
- (2) The name, address and telephone number and address of the manufacturing facility. Post office box numbers will not constitute compliance with the requirements of this section.

- (3) For the five (5) years preceding the date of the renewal application, the annual output in liter of e-liquid manufactured by the applicant.
- (4) The full legal name, social security number, date of birth, title, and address of the facility manager(s) responsible for the manufacturing facility
- (5) A certification by the applicant that the security protocol submitted with the initial application and approved by the ATC is still in place and will continue throughout the life of the renewal.
- (6) Certification by the Security firm that they continue to comply with all security requirements required by this title.
- (7) Statement of verification that the manufacturing process employed by the applicant is compliant with Title 7.1 requirements.
- (8) Written consent authorizing the ATC through its duly appointed agents to conduct the necessary criminal background checks required by this title.
- (9) Written consent authorizing the ATC or its duly appointed agents to enter the premises unannounced and during regular business hours to conduct random sample testing and audits.
- (10) A nonrefundable application fee in the amount of five hundred (\$500).
- (11) Any other information as deemed appropriate by the commission that is relevant to the renewal application.

(b) The applicant is responsible for notifying the Indiana ATC within ten (10) business days if any information in the initial application changes. Failure to make a timely and accurate notification about information changes may result in the denial of the application

905 IAC 1-54-7 Transfer of permits

Authority:

Affected:

Sec. 7. (a) Permits are transferable to another person or location only with ATC approval

(b) Permits shall be transferable upon a showing to the ATC that;

- (1) The permit has not been suspended or revoked and is in good standing, and,
- (2) The new permit holder and location meets all of the requirements as required by this article.

905 IAC 1-54-8 E-liquid manufacturing

Authority:

Affected:

Sec. 8. (a) In order to be in compliance with Indiana Code Title 7.1 relating to e liquid manufacturing the manufacturing facility must demonstrate compliance with the following:

- (1) An e-liquid container must use a child proof cap that has the child resistance effectiveness set forth in 16 CFR 1700.15(b) (1);
- (2) An e-liquid container must use a tamper evident package;
- (3) E-liquid containers must be labeled;
- (4) Labels on e-liquid containers must identify all ingredient(s) including nicotine;
- (5) Each e-liquid production must be identified by a scannable identifiable code, a scannable batch number and date of production;
- (6) Labels on containers must include the scannable production code, date of production and scannable batch number;
- (7) E-liquid container label must show a "best if used by" date be distributed by the manufacturer and sold by the manufacturer or the retailer by the earlier of either the expiration or two (2) years of the date of manufacture;
- (8) Manufacturing facility must conduct all mixing and bottling activities in a clean room as defined in Indiana Code Title 7.1;
- (9) Manufacturer must take reasonable steps to ensure that an unauthorized ingredient is not included in any e-liquid produced by manufacturer for sale in Indiana;
- (10) Manufacturer must take reasonable steps to ensure that all ingredients used in the production of e-liquid are stored in a secure area accessible only by authorized personnel;
- (11) Manufacturer must maintain a remotely monitored security system at the facility in all areas where e-liquid is mixed, bottled, packaged, and stored;
- (12) Manufacturer shall have a high-security key system that limits access to areas where e-liquid is mixed;
- (13) Manufacturer's facility must be subject to twenty-four (24) hour video recording where e-liquids are mixed, bottled, and stored. The video recordings must be retained for at least one hundred and eighty (180) days and are subject to ATC audit for quality, purity, and compliance reviews;
- (14) Manufacturer must take reasonable steps to ensure that only authorized personnel have access to secured areas of the facility where e-liquid is mixed, bottled, and packaged;
- (15) Manufacturer must store and maintain three (3) ten (10) milliliter sample bottles from each production batch of more than two (2) liters for a period of not less than three (3) years in a secure, limited access area with recorded video surveillance; and
- (16) A production log must be maintained listing the following;
 - (A) Date and time the e-liquid was produced
 - (B) The name of the product manufactured
 - (C) The amount of the product produced in liters
 - (D) The code and batch number
 - (E) The person(s) responsible for the mixing and bottling.

905 IAC 1-54-9 Random samples

Authority:

Affected:

Sec. 9 ATC requires that each approved e-liquid manufacturer have at least three (3) different products tested annually for safety, quality and purity purposes: Names of independent laboratories to be used will be maintained by the ATC and posted on the ATC website. ATC will select the three (3) products to be sampled from the listing of products to be manufactured submitted with the e-liquid manufacturer permit application. All costs associated with testing will be paid directly by the permittee to the testing facility. Failure by the permittee to submit to the required testing or failing to promptly pay for testing may lead to disciplinary action at the discretion of the ATC. Such action by the ATC could include fines, suspension of or revocation of the permit. Laboratories will test for the ingredients listed for the products and to determine if the product contains any ingredients other than those listed on the product label. Results from the independent laboratory testing will be sent to the ATC and shared with the permittee. At the discretion of the ATC, products containing ingredients other than those listed as ingredients with the ATC will be subject to retesting including possible enforcement action under IC 7. All costs associated with retesting will be paid by the permittee.

905 IAC 1-54-10 Violations and penalties

Authority:

Affected:

Sec. 10. (a) Violations involving this article will be cited by the Indiana State Excise police and prosecuted by the ATC prosecuting Attorney subject to the following procedure;

(1) Procedure

- (A) Permittee will receive notice that a formal violation has been filed from the ATC Prosecutor
- (B) Along with the notification of the formal charges the ATC Prosecutor will include an offer to settle the violation.
- (C) Penalties may range from reprimand, to fine and civil penalties not to exceed ten thousand dollars (\$10,000) and include suspension for up to one year (1) and /or or revocation of the permit.
- (D) Permittee has fourteen days (14) from the date appearing on the notice to accept or reject the settlement offer.
- (E) Rejecting the settlement offer will result in the matter being set for a contested hearing in front of a hearing officer and in compliance with Indiana Administrative Code relating to contested hearings.
- (F) The permittee may appeal and adverse ruling to the hearing judge to the full commission.
- (G) The full commission's ruling on an appeal will be considered the final agency action and is subject to judicial review.

(2) Presumptive Revocation – A case for presumptive revocation of the permit is created when permittee admits to or has been found in violation of any of the following at least six (6) times in any one hundred eighty day period

- (A) Knowingly selling to a minor, or
- (B) Knowingly purchasing from a unapproved manufacturer, or
- (C) Knowingly selling e-liquid that has been tampered with

(b) The presumptive revocation is rebuttable and the burden to show that the permit should not be revoked is on the permittee.

TITLE 905 ALCOHOL AND TOBACCO COMMISSION

Emergency Rule
LSA Document #

DIGEST

Temporarily adds noncode provisions for licensing requirements for e-liquid manufacturers.
Statutory authority: IC 4-22-2-37.1; IC 7.1-7-3-3. Effective January 1, 2016.

SECTION 1. (a) The purpose of this document is, in the absence of federal regulations, to protect public health and safety by:

- (1) ensuring the safety and security of e-liquid manufactured for sale in Indiana;**
- (2) ensuring that e-liquid manufactured or sold in Indiana conforms to appropriate standards of identity, strength, quality, and purity; and**
- (3) ensuring that e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health and safety.**

(b) This document applies to the commercial manufacturing, bottling, selling, bartering, or importing of e-liquid products in Indiana and the sale, possession, and use of e-liquid products in Indiana.

SECTION 2. Any e-liquid or nicotine product, including nonrefillable sealed cartridge electronic cigarettes, sold for use in Indiana may not be sold to anyone less than eighteen (18) years of age.

SECTION 3. (a) The definitions in IC 7.1-7-2 and this section apply throughout this document.

(b) "Commission" or "ATC" means the Indiana Alcohol and Tobacco Commission

(c) "Packaging" means the process by which e-liquid is bottled in a tamper evident package with a child resistant cap and labeled in compliance with IC 7.1-7. The term does not include the process of preparing to ship or distribute already manufactured and packaged e-liquid.

SECTION 4. (a) Anyone involved in manufacturing an e-liquid for sale to retailers or distributors of e-liquid in Indiana must first obtain an e-liquid manufacturer's permit from the commission. Initial applicants for an e-liquid manufacturer's permit must complete and submit the application prescribed by the commission before June 30, 2016. The application must include the following:

- (1) Business name, mailing address, and telephone number of the applicant.**
- (2) Business name, telephone number, and address of the manufacturing facility.**
- (3) Full legal name, address, date of birth, Social Security number, and primary telephone contact number for each owner.**
- (4) Name, telephone number, date of birth, Social Security number, title, and address of the facility managers responsible for the manufacturing facility.**
- (5) Floor plans, marked as confidential under IC 7.1-7-3-2, of the manufacturing facility that show the layout of the entire manufacturing facility including the following:**
 - (A) The clean room.**
 - (B) The storage room where sample bottles are stored as required by IC 7.1-7-4-6.**



- (C) All entrances, exits, and interior doors.
- (D) All areas open to the public, including areas used for sales or distribution of e-liquids.
- (6) An executed security agreement showing compliance with the requirements of IC 7.1-7-4-1(d)(3) and IC 7.1-7-4-6(b)(10) through IC 7.1-7-4-6(b)(15). A security agreement will be treated as confidential and only be released pursuant to a court order.
- (7) A verified statement from the security firm that includes the following:
 - (A) Name of the employee of the security firm who is accredited by the Door and Hardware Institute as an architectural hardware consultant.
 - (B) Name of the employee of the security firm who is accredited by the International Door Association as a certified rolling steel fire door technician.
 - (C) Name of the employee of the security firm who is a locksmith.
 - (D) Statement that the security firm has at least one (1) year of commercial experience, in the preceding year, with the following:
 - (i) Video surveillance system design and installation with remote viewing capability from a secure facility.
 - (ii) Owning and operating a security monitoring station with ownership control and use of a redundant offsite backup security monitoring station.
 - (iii) Operating a facility that modifies commercial hollow metal doors, frames, and borrowed lights with authorization to apply the Underwriters Laboratories label(8)
- (8) Statement that no individuals, corporations, limited liability companies, limited liability partnerships, partnerships or stock owners, members, or partners of such entities with an interest, either directly or indirectly, have any interest, either directly or indirectly, in any e-liquid manufacturer, distributor, or retailer.
- (9) A verified statement that all products manufactured for distribution in Indiana contain only the ingredients listed in IC 7.1-7-5-1(a).
- (10) An addendum, marked as confidential, that provides a product listing that complies with Section 8 of this document.
- (11) A verified statement that the facility will comply with manufacturing processes required by IC 7.1-7 and this document.
- (12) A verified statement that equipment used is easily cleanable as defined in 410 IAC 7-24-27(a).
- (13) A copy of the results of a national criminal history background check for any owner, member, and facility manager or all listed on the permit application which shall be:
 - (A) performed by the Indiana state police department or the equivalent law enforcement agency in another state; and
 - (B) paid directly by the applicant to the entity performing the background check.
- (14) The submission and subsequent approval of an application under this Section and for the life of the permit operates as consent for the commission or its duly appointed agents to enter the approved manufacturer's premises during normal business hours to conduct physical inspections, product sampling for compliance with requirements of IC 7.1-7, or for the purposes of an audit.
- (15) A nonrefundable application fee of one thousand dollars (\$1,000).
- (16) Any other information as deemed appropriate by the commission to complete review of the application.

(b) The applicant is responsible for notifying the commission within ten (10) business days if any information in the initial application changes. Failure to make a timely and accurate notification about information changes may result in the denial of the application.

SECTION 5. (a) The commission shall complete its review and take final action upon the application within sixty (60) days after receiving all information and documentation required by IC 7.1-7 and this document, including, but not limited to the following:

- (1) The certification by the security firm that the manufacturing facility is in compliance with the requirements of IC 7.1-7-4-1(d)(3) and IC 7.1-7-4-6(b)(10) through IC 7.1-7-4-6(b)(15). A fully compliant service security agreement is executed with the final copy submitted to commission.
- (2) All criminal backgrounds checks are final.
- (3) Any other outstanding matters required by the commission are satisfied.

(b) An approved manufacturer's permit will not be required for renewal until five (5) years after the date of the initial application's approval or the last renewal.

(c) For an out of state or out of country manufacturing facility that the commission is unable to physically inspect, arrangements may be made for an independent provider approved by the commission to perform such inspection. The out of state approved inspecting facility will be required to submit the results of the inspection directly to the commission via first class mail.

(d) All costs associated with the inspection and reporting will be paid by the applicant.

SECTION 6. (a) Applications for renewals of existing permits must be submitted to the commission on an application form prescribed by the commission at least sixty (60) days before the expiration date of the existing permit and must include the following:

- (1) The business name, mailing address, and telephone number of the applicant.
- (2) The business name, physical address, and telephone number of the manufacturing facility.
- (3) The full legal name, address, and primary telephone contact number for each owner.
- (4) The full legal name, address, and primary telephone contact number for each facility manager responsible for the manufacturing facility.
- (5) For the five (5) years preceding the date of the renewal application, the annual output in liters of e-liquid manufactured by the applicant.
- (6) An executed security agreement, marked as confidential, showing compliance with the requirements of IC 7.1-7-4-1(d)(3) and IC 7.1-7-4-6(b)(15).
- (7) Evidence that the security firm complies with the requirements of IC 7.1-7 by either:
 - (A) a verified statement by the security company that the information provided in the initial application or most recent renewal applicant continues to be correct; or
 - (B) a verified statement as required by Section 4(a)(7) of this document that includes any changes to the security company.
- (8) A Verified statement that all products manufactured for distribution in Indiana contain only the ingredients listed in IC 7.1-7-5-1(a).
- (9) A Verified statement that the manufacturing process employed by the applicant complies with the requirements of IC 7.1 and this document.
- (10) Written consent allowing the state police department to conduct a state or national criminal history background check on any person listed on the application.
- (11) Written consent allowing the commission, if a permit is renewed to the applicant, to enter the premises where the e-liquid is manufactured to conduct physical inspections, sample the product to ensure the e-liquid meets the requirements of e-liquid set forth in IC 7.1-7, and perform an audit.
- (12) A nonrefundable application fee in the amount of five hundred dollars (\$500).

(13) Any other information as deemed appropriate by the commission that is relevant to the renewal application.

(b) The applicant is responsible for notifying the commission within ten (10) business days if any information in the initial application changes. Failure to make a timely and accurate notification about information changes may result in the denial of the application.

SECTION 7. (a) As used in this Section, "sample" means the three (3) ten(10) milliliter sample bottles from each production batch of more than two (2) liters required to be stored or maintained by IC 7.1-7-4-6-(b)(15).

(b) Permits are transferable to another person or location only with commission approval.

(c) Permits shall be transferable upon a showing to the commission that:

(1) the permit has not been suspended or revoked and is in good standing; and

(2) the new permit holder and location meet all of the requirements as required by this document.

(d) An e-liquid manufacturer transferring the location of the permit shall maintain the samples in a secure, limited access area during the transfer of location by complying with the following:

(1) The e-liquid manufacturer must notify the commission of the anticipated date the samples will be removed from the original location and the anticipated date the samples will be moved into the new location.

(2) Samples may only be removed from the secure, limited access area with recorded video surveillance at the original location by designated employees of the e-liquid manufacturer.

(3) Samples removed from the secure, limited access area with recorded video surveillance at the original location must be placed immediately in a secure, limited access container or vehicle for transporting to the new permit location.

(4) Video surveillance may not be removed or disconnected from the secure, limited access area until all samples are removed to the secure, limited access container or vehicle.

(5) The secure, limited access area for the storage of samples at the new location must have operational video surveillance before samples may be placed in the area.

(6) The e-liquid manufacturer must notify the commission of the completion of the transfer within five (5) days after the completion of the relocation of the samples and equipment.

(7) The e-liquid manufacturer must maintain a list of employees who had access to the samples during the transfer for a period of three (3) years.

SECTION 8. (a) The manufacturer shall provide a product listing to the commission at the time of the initial application for all e-liquid products manufactured in production batches of more than two (2) liters.

(b) The product listing shall include:

(1) the product name;

(2) for each product, the percentage of nicotine; and

(3) the original date of manufacture of each product.

(c) The manufacturer shall notify the commission within thirty (30) days of the following:

- (1) The manufacture of a new e-liquid product manufactured in production batches of more than two (2) liters and the original date of manufacture.
- (2) The manufacture of an existing e-liquid product under a new or amended product name and the original date of manufacture under the new or amended product name.
- (3) The discontinuation and final manufacture date of an e-liquid product.
- (4) The final date of manufacture of a discontinued product.

(d) The manufacturer shall maintain a record of each ingredient used in a production batch for three (3) years and shall provide this information to the commission upon request.

SECTION 9. In order to comply with IC 7.1 relating to e-liquid manufacturing, the manufacturing facility must demonstrate compliance with the following:

- (1) An e-liquid container must use a child proof cap that has the child resistance effectiveness set forth in 16 CFR 1700.15(b)(1).
- (2) An e-liquid container must use a tamper evident package.
- (3) E-liquid containers must be labeled.
- (4) Labels on e-liquid containers must identify all ingredients including nicotine.
- (5) The label on an e-liquid container must include a scannable code, including a quick response code, tied to the batch number and date of production. Labels on containers must include date of production, batch number, and the scannable code.
- (6) An e-liquid container label or tamper resistant packaging must include a "best if used by" or a manufacture date and be distributed by the manufacturer and sold by the manufacturer or the retailer by the earlier of either the "best if used by" or two (2) years of the date of manufacture.
- (7) The manufacturing facility must conduct all mixing and bottling activities in a clean room as defined in IC 7.1.
- (8) The manufacturer must take reasonable steps to ensure that an unauthorized ingredient is not included in any e-liquid produced by manufacturer for sale in Indiana.
- (9) The manufacturer must take reasonable steps to ensure that all ingredients used in the production of e-liquid are stored in a secure area accessible only by authorized personnel.
- (10) The manufacturer must maintain a remotely monitored security system at the facility in all areas where e-liquid is mixed, bottled, packaged, and stored.
- (11) The manufacturer shall have a high-security key system that limits access to areas where e-liquid is mixed.
- (12) The manufacturer's facility must be subject to twenty-four (24) hour video recording where e-liquids are mixed, bottled, and stored. The video recordings must be retained for at least one hundred eighty (180) days and are subject to commission audit for quality, purity, and compliance reviews.
- (13) The manufacturer must take reasonable steps to ensure that only authorized personnel have access to secured areas of the facility where e-liquid is mixed, bottled, and packaged.
- (14) The manufacturer must store and maintain three (3) ten (10) milliliter sample bottles from each production batch of more than two (2) liters for a period of not less than three (3) years in a secure, limited access area with recorded video surveillance.
- (15) A production log must be maintained listing the following:
 - (A) Date and time the e-liquid was produced.
 - (B) The name of the product manufactured.
 - (C) The amount of the product produced in liters.
 - (D) The code and batch number.

(E) Any person responsible for the mixing and bottling.

SECTION 10. (a) The commission shall require an e-liquid manufacturer to have at least three (3) different products tested annually by one (1) of three (3) independent laboratories approved by the commission for safety, quality, and purity purposes.

(b) The commission will select the three (3) products to be tested pursuant to subsection (a) from the product listing provided to the commission under Section 8 of this document.

(c) Failure by the e-liquid manufacturer to submit or pay the costs of a product testing required by subsection (a) will result in disciplinary action by the commission that may include fines, suspension, and revocation of the permit.

(d) The commission may require the laboratory to test for any of the following:

- (1) Nicotine.
- (2) Ingredients listed on the label.
- (3) Contaminants.
- (4) Illegal drugs.

(e) At the discretion of the commission, products that test positive for ingredients other than those listed on the label or on the ingredient list maintained by the e-liquid manufacturer under section 8 of this document may be subject to retesting at the cost of the e-liquid manufacturer.

Section 11. Sections 1 through 10 of this document take effect January 1, 2016.