



## **SENATE ENROLLED ACT 1 - A NEW DAY FOR INDIANA VAPOR**

Senate Enrolled Act 1 is the culmination of months of planning, drafting, lobbying and negotiating by Indiana Smoke-Free Alliance, Vapor Technology Association, and Krieg DeVault, LLP, that resulted in elimination of a legislated monopoly that strangled vapor businesses in Indiana for two years. The result of our concerted effort is remarkable: we have re-opened the Indiana market to all vapor businesses and, at the same time, built credibility and trust for the true vapor industry in Indiana amongst members of the Indiana General Assembly.

On April 21, 2017, the Indiana General Assembly approved Senate Bill 1. The bill was subsequently signed by the Governor and became effective on April 27, 2017.

### **ANALYSIS OF PROVISIONS IN SENATE ENROLLED ACT 1**

#### **What Are the Security Requirements?**

- None. The security requirements in Indiana law which were previously applicable to in-state and out of state manufacturers have been removed. Eliminating these bizarre requirements was a key emphasis of Senate Bill 1 and these provisions were removed from every draft of Senate Bill 1.

#### **Who Does the New Law Regulations Apply To?**

- The bill applies to the manufacturing, bottling, selling, bartering, and importing of e-liquid in Indiana
  - The bill does *not* apply to a manufacturer of a closed system vapor product, except as specifically provided in the bill.
  - Note "Manufacturer of Closed System Vapor Product" means a manufacturer of vapor products whose closed system vapor products are for sale in Indiana, but that does not produce open system vapor products that are for sale in Indiana.
- E-liquids
  - Include substances that may or may not contain nicotine intended to be used in a vapor product.
  - *All Manufacturers, Distributors, and Retailers who sell products in Indiana must be licensed.*

#### **How Can I Do Business in Indiana Again?**

- Manufacturers will apply to the Indiana ATC for a license. The ATC is now accepting licensure applications. (More on this below).
  - Note The ATC must approve or deny a license within 60 days of receiving the application.
    - This time frame was specifically created in the bill by the ISFA and VTA to ensure fair treatment of all applicants.
  - A permit will be valid for a period of five years.
  - The manufacturing license application fee is \$1,000 dollars.
  - A license may be renewed. Renewals are \$500 dollars.



- Manufacturers will have to provide contact information, and verify they will comply with applicable good manufacturing practices as well as applicable ingredient listing requirements under the federal deeming rule when such rules are enacted.
- Certain persons convicted of certain Indiana felony offenses or certain federal offenses are not eligible for a manufacturers license.
- Distributors must have a valid manufacturers license or a distributors license under current tobacco regulations.
- Retailers must have a valid sales certificate issues by the ATC.

#### **What are the Packaging & Labeling Requirements?**

- Products must not be adulterated and must be sold in tamper evident packaging as defined under the Act.
- Manufacturing facilities must comply with the following
  - Child proof caps compliant with the federal poison prevention packaging standards
  - Nicotine addictiveness warnings required under 21 CFR 1143.3
- Labels must include
  - An identifiable and trackable code
  - the Indiana e-liquid manufacturer permit number
  - Manufacturing date
  - A separate designation that "This product contains nicotine"
  - Beginning in 2018, and until specific rules are adopted by the commission: "WARNING THIS PRODUCT CONTAINS NICOTINE. NICOTINE IS AN ADDICTIVE CHEMICAL."
- A manufacturer must submit to random site visits by the ATC.

#### **What are the Reporting and Record Keeping Requirements?**

- All distributors and retailers shall maintain all invoices for at least two years.
- Reporting:
  - All manufacturers must annually submit to the ATC:
    - each new product that the manufacturer is producing and selling in Indiana with a list of contents and ingredients by volume;
    - Whether the manufacturer has stopped producing products previously produced and sold in Indiana;
      - Note: The above requirements will NOT apply if the manufacturer certifies to the ATC by October 1 of each year, that each of the manufacturers products which are sold in Indiana are registered with the FDA.
    - Milligrams per milliliter of nicotine in each product the manufacturer produces; and
    - Milliliters of each product sold in the current year.
- All reporting to the ATC is confidential and the ATC may not disclose the reporting for any reason.



### **Online Sales**

- The bill creates a clear path for online sales in Indiana and expressly allows online sales in Indiana while providing safeguards to ensure that only those over 18 years of age are allowed to purchase vapor products.
  - Requires Age Verification
  - Requires purchases to be paid in full prior to the product shipping
  - Has to have the statement "E-liquids: Indiana law prohibits the sale of this product to a person who is less than 18 years of age" on a document that accompanies the shipment

### **Violations of the Act**

- Any violation of the Food, Drug, and Cosmetic Act which an Indiana manufacturer is required to comply with under SEA 1 shall be considered a violation of Indiana law.
- Any licensee under SEA 1 who is in violation of the Act could be fined up to \$10,000.
- A person who knowingly sells a vapor product to a minor is guilty of a Class C Infraction.

### **What was Removed from Indiana Law**

- Security Requirements
- ATC Jurisdiction
- The ability to create arbitrary rules for licensure
- The ability to test e-liquids
- The requirement that the ATC approve vapor product ingredients.
- A proposed online sales ban which was fought by ISFA & VTA.

## **GUIDANCE FROM MEETING WITH INDIANA ATC**

Much like the e-liquid industry, the Indiana Alcohol & Tobacco Commission (ATC) is working through a number of issues of interpretation surrounding the implementation of Senate Enrolled Act 1. They have pledged to work with the Indiana Smoke Free Alliance and Krieg DeVault LLP as their deliberations proceed.

During the recent VTA/ISFA webinar *A New Day for Indiana Vapor* (watch it [here](#)), participants asked a number of questions regarding the regulations and how the ATC would enforce or interpret those regulations. ISFA and Krieg DeVault agreed to present those questions during their meeting with ATC on May 8, 2017.

### **Permits and licenses**

- The Manufacturing Permit Application is currently located on the ATC website at [http://www.in.gov/atc/files/E-Liq%20Mfg%20App%20Form%2052973%20-%205\\_9\\_17.pdf](http://www.in.gov/atc/files/E-Liq%20Mfg%20App%20Form%2052973%20-%205_9_17.pdf). This includes changes to conform with the final version of SEA 1, along with the changes to the list of officers, directors, or members of business applicants that must be listed on the permit application.



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- The ATC is currently accepting applications and will formally announce approved applications during their regular ATC meetings held on the first and third Tuesdays of each month. It is possible that some permits may be approved during the next meeting on May 16, 2017.
- Any entity that sells direct to consumers, including manufacturers and distributors, will be required to obtain a tobacco sales certificate (<http://in.gov/atc/2474.htm>) in addition to any other permit or license as required by the law.
- There may be additional business registration requirements imposed on companies, including out of state manufacturers and distributors, beyond the specific e-liquid permitting requirements. There may be additional tax concerns that also need to be considered. Please contact us if you need further guidance.

### **Labeling**

- All e-liquids manufactured for sale in Indiana must meet the labeling requirements as outlined in SEA 1. That includes the “identifiable and trackable code,” the manufacturing date, and the Indiana e-liquid manufacturer permit number and nicotine warning statement. The ATC is currently discussing what nicotine notification will be required at this time. However, the Federal Warning statement, “WARNING THIS PRODUCT CONTAINS NICOTINE. NICOTINE IS AN ADDICTIVE CHEMICAL” is acceptable.
- The specific label information must be included on the bottle or container (as defined by the container that actually comes into contact with the e-liquid itself). The permit number can be attached to the bottle or container using a sticker or label.
- Products manufactured by a manufacturer that is approved by the commission before July 1, 2017 may be distributed and sold for retail without meeting the new labeling requirements until the expiration date of the e-liquids.

### **Miscellaneous**

- While the ATC will take actions necessary to protect the consumer and the general public, their efforts will largely be complaint-driven, as the consumer and the industry participants themselves are often the best source of information for a lack of compliance with state laws and regulations. Certainly this approach could change as needs arise.
- Distributors and retailers may retain their invoices in either electronic or paper format.
- SEA 1 prohibits the self-service of all e-liquids and their component parts even in retail locations that prohibit entry to a person under the age of 18.
- The ATC is currently discussing whether sampling is allowed under SEA 1 given the requirements that an e-liquid container use a child-proof cap and tamper evident packaging.

### **QUESTIONS**

If you have any questions on these items or need further clarification, please contact:

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