

Economic Impact Statement

LSA Document #15-290

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

The rule imposes minimal additional requirements on small businesses beyond that which is required by [IC 7.1-7](#). This statement outlines the requirements on small businesses and divides those requirements into two categories: requirements that are imposed by both the statute and the rule and requirements that are imposed by only the rule. The Alcohol and Tobacco Commission (ATC) considered alternatives to the requirements imposed by the rule and concluded that these requirements impose the least burden on small businesses while still allowing the ATC to fulfill the duties and responsibilities of the ATC in [IC 7.1-7-3-2](#).

1. It is indeterminable at this time the number of small businesses that will be subject to the proposed rule. The ATC has never licensed or tracked the number of e-liquid manufacturers. The ATC does not have an estimate of the number of e-liquid manufacturers in Indiana.

2. E-liquid manufacturers will be required by both statute and rule to keep records and report as described in the sections below.

(A) Output of e-liquid: E-liquid manufacturers will be required to provide in their initial applications the projected output in liters per year of e-liquid of the manufacturing facility. E-liquid manufacturers will be required to provide in their renewal applications the annual output in liters of e-liquid of the manufacturing facility for the five (5) years preceding the year of the application. The permit term for e-liquid manufacturers is five (5) years. This will require a small business to keep records annually of e-liquid output and report this amount to the ATC every five (5) years.

(B) Batch number and scannable code: E-liquid manufacturers will be required to assign a batch number to each batch of e-liquid manufactured, maintain a list of the batch numbers, and include the batch number on the label. Additionally, the e-liquid manufacturer will be required to attach a scannable code to the label that is tied to the batch number.

(C) Storage of sample bottles: E-liquid manufacturers must store and maintain three (3) ten (10) milliliter samples 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.

(D) Testing: E-liquid manufacturers must submit e-liquid samples for testing at the manufacturer's expense. The ATC will select at random up to three (3) e-liquid samples per year for testing.

(E) Packaging and labeling requirements: E-liquid manufacturers are required to put a label on the e-liquid container that identifies active ingredients, includes a separate designation if the product contains nicotine, includes a batch number and an expiration date, and contains a scannable code tied to the batch number.

3. E-liquid manufacturers will be required by rule to keep records and report as described below.

(A) Product listing: E-liquid manufacturers will be required to maintain a product listing that includes the product name, the percentage of nicotine for each product, and the original date of manufacture for each product. The manufacturer will be required to submit this product listing to the ATC at the time of the initial application. Changes to the product listing, including new e-liquids produced by the manufacturer, must be reported the ATC within thirty (30) days of the date they are initially manufactured.

(B) Ingredient list: E-liquid manufacturers will be required to maintain a listing of ingredients used in a production batch for three (3) years. The ingredient list will not be reported to the ATC, but shall be available upon request by the ATC.

4. It is indeterminable at this time the annual economic impact that compliance with these requirements will have on all small businesses subject to the rule. The total annual economic impact of compliance with these requirements would vary based on the amount of e-liquid manufactured by each e-liquid manufacturer. Additionally, the ATC does not know at this time the number of e-liquid manufacturers that will apply for an e-liquid manufacturing permit.

5. The product listing and the ingredient list are not specifically required by statute, but are necessary to the ATC's enforcement and administration of statutory and regulatory requirements for e-liquid manufacturers.

The ATC's duties and responsibilities as stated in [IC 7.1-7-3-2](#) include:

(A) Auditing random samples maintained by the manufacturer to ensure the safety and quality of the e-liquid and that the e-liquid meets the requirements in this article.

(B) Ensuring, in coordination with the Indiana State Department of Health, that the e-liquid manufactured and sold in Indiana conforms to appropriate standards of identity, strength, and purity.

Through discussions with manufacturers and retailers in the e-liquid industry, the ATC determined that it is common for a manufacturer to produce e-liquid under different brands names, in different flavors within a brand name, and in different nicotine levels for each flavor. The product listing will assist the ATC in selecting random samples for audit by providing a list of the different e-liquids produced by each manufacturer. The product listing will also allow the ATC to easily identify which products are produced by a permitted manufacturer and, therefore, can be sold at retail in Indiana.

The ingredient list allows the ATC to request ingredient information for a specific batch of e-liquid, without requiring continuous reporting to the ATC. This ingredient information may allow the ATC to review product ingredients to ensure that the product conforms to appropriate standards of identity, strength, and purity without always requiring a manufacturer to incur the expense of testing. Additionally, it allows the manufacturer or the ATC to identify ingredients in a specific batch back to the manufacturer of the ingredient components of the e-liquid in the event there are concerns about a specific flavoring, nicotine, etc.

6. Regulatory flexibility analysis: Due to the requirements of [IC 7.1-7](#), the ATC does not have regulatory flexibility on the requirements of paragraphs 2(A) through 2(E) above.

The alternatives to the product listing, such as requiring reporting to the ATC on each batch produced, create additional burdens on the manufacturers. The ATC considered requiring the manufacturers to report the ingredients used in each batch to the ATC, but after discussions with members of the industry, concluded that this was too great a burden on the manufacturer. Another alternative to requiring the manufacturer to maintain an ingredient list is to require more than just the minimum random sample testing of products. By statute, the testing of random samples is done at the expense of the e-liquid manufacturer and additional testing would place additional administrative and financial burdens on small businesses.

The ATC considered alternatives to the requirement that the product listing be updated with the ATC within thirty (30) days of a new product being manufactured. Requiring the product listing to be updated sooner would place a greater burden on the manufacturer. Allowing the product listing to be updated later than thirty (30) days may result in unnecessary enforcement actions by Excise if a product is sold at retail that is not included in an updated product listing with the ATC.

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