The Smoke-Free Alternatives Trade Association

Responsible Industry Network Program

Informational Overview

Smoke-Free Alternatives Trade Association's Youth Access Policies

- As the national trade association representing businesses in the vapor industry, the Smoke-Free Alternatives Trade Association (SFATA) requires its members to uphold the highest standards of excellence and adhere to its Member Code of Responsible Conduct.

- SFATA has had a strict ADULT ONLY sales policy and required its members to have age verification processes in place since 2012.

- SFATA believes that a controlled distribution will enhance and advance FDA's goal of restricting youth access to vapor products, as described in FDA's Youth Tobacco Prevention Plan.

- SFATA's Responsible Industry Network (RIN) program requires adherence to a detailed series of standards and protocols that serve to protect the consumer and public health. Strict adherence is required for continued participation in the RIN network of manufacturers, distributors, and retailers.

RIN Mission

RESPONSIBLE INDUSTRY NETWORK

The mission of SFATA's Responsible Industry Network is to protect its members and the public by administering marketing and post-market monitoring in accordance with FDA guidelines and regulatory structure. RIN creates a pathway that ensures economic, cultural, and social growth for our manufacturer, distributor, and retailer members and their communities.

In short, RIN is a comprehensive, cooperative industry network that prevents youth exposure while preserving adult access to tobacco harm reduction products.

Tobacco Harm Reduction

Modified Tobacco

Recently, there has been a lot of debate about the role of modified tobacco products in reducing tobacco-related harm.

WHO

The World Health Organization's Study Group on Tobacco Product Regulation, Technical Report Series 989, recommended establishing maximum levels for certain toxic constituents in tobacco products.

FDA

FDA's Comprehensive Plan for Tobacco and Nicotine Regulation includes a scientific review of implementing product standards for safety, as well as regulatory policy for correcting misperceptions about nicotine.

Flavors

Non-tobacco flavors, daily vaping, and modifiable e-cigarette devices may help some smokers abstain from cigarette smoking via transitioning to exclusive e-cigarette use…

Consumers

Vapers use a variety of flavors. 63.1% prefer a non-tobacco flavor. Those vaping candy or fruit flavors are more satisfied (compared to smoking) than vapers using tobacco flavor[1] – which is why we fight so hard to keep flavors accessible to adult consumers!

PMTA Requirements

- For a PMTA to be approved for a marketing order, FDA "intends to consider how an applicant will target the marketing of its new tobacco product to reach its intended consumers of legal age and to assess potential effect on nonusers. FDA will also consider how the applicant intends to minimize the extent to which youth can access the product and are exposed to its marketing."[2]

- "If the PMTA does not address youth access to the product, youth exposure to the product's labeling, advertising, marketing, and promotion, and youth initiation, such as describing how it proposes to restrict the sale or distribution of its product to limit potential youth access to the product … FDA may be unable to determine that the applicant has made a showing that permitting the marketing of the new tobacco product would be appropriate for the protection of public health."[3]

FDA Guidelines for PMTA

- Under Section 910(c)(4) of the FD&C Act, products submitted for PMTA must be deemed appropriate for the protection of public health in order to receive a market order.
  - Section 910(c)(4) considers risks and benefits to the population based on:
    - Impact on cessation
    - Impact on initiation (Youth)
- Section 910(f) of the FD&C Act allows FDA to require that applicants establish and maintain records, and submit reports to enable FDA to determine, or facilitate a determination of, whether there are or may be grounds for withdrawing or temporarily suspending an order.

How the RIN Program Addresses PMTA Requirements and FDA Guidelines

- SFATA believes its RIN program will allow the association to create a working partnership between program participants and FDA which will ease the burden on each.

- SFATA will act as liaison* between FDA and RIN participants to ensure reporting is performed in a streamlined, timely, and on-going basis.

- SFATA's RIN program will monitor participants through data collection and through its strategic partners like WeCard and TraceVerify.

- Post-market reporting requirements will vary by submission. SFATA will work with each RIN participant to assist them with their requirements*.

*Where applicable

RIN Program Objectives

SFATA's RIN program will help both FDA and RIN participants protect public health interests by:

- Facilitating and monitoring compliance of RIN participant companies to SFATA's mission and guiding principles, as well as monitoring adherence to federal, state, and local regulatory requirements.*
- Controlling product marketing and sales by limiting access to adults via a controlled distribution buying network.
- Enabling a robust product tracking and tracing process via TraceVerify or other measures that allow a product RFID tag/QR Code to trace the product to the purchaser ID at the point of sale, resulting in significant reduction to straw purchases.
- Creating accountability for manufacturers, distributors, and retailers with corrective actions and consequences for non-compliance, ultimately including loss of program participation and access to industry partners.
- Requiring retail participants to sell products purchased from RIN manufacturers and distributors, ensuring a closed-loop system of control.

*Where applicable

RIN Program Objectives Cont.

SFATA's RIN program will help both FDA and RIN participants protect public health interests by:

- Generating and compiling streamlined and comprehensive post-market surveillance data from a single source, rather than from multiple sources to multiple sources in multiple formats – a HUGE WIN for all parties!
- Establishing a reporting and records system that will help eliminate youth vapor products and secure their access for adult consumers.
- Assisting the efforts of regulatory and law enforcement authorities to deter youth access and straw purchasers.
- Creating a system that rewards responsible merchants and helps guide the vapor industry in the direction of excellence.

*Where applicable

RIN Program Overview

- The RIN program is intended to reduce the resource burden on responsible vapor industry participants, FDA, and other regulatory agencies while furthering the public health goals of tobacco harm reduction.

- The RIN program establishes a robust reporting and record system that will help to minimize youth access to vapor products while also working to eliminate straw purchases.

- RIN retail participants are committed to being “adult-only” establishments, as defined by: “requiring each person present to provide a government-issued identification showing a photograph and a date of birth indicating the holder is at least 21 years of age.” Parents with minors present are allowed in, when necessary, to obtain supplies.

- RIN manufacturer participants must have submitted a PMTA and follow a set of GMP standards. This both ensures a high-quality product for consumer use, as well as elevates RIN participant manufacturers above non-participant peers.

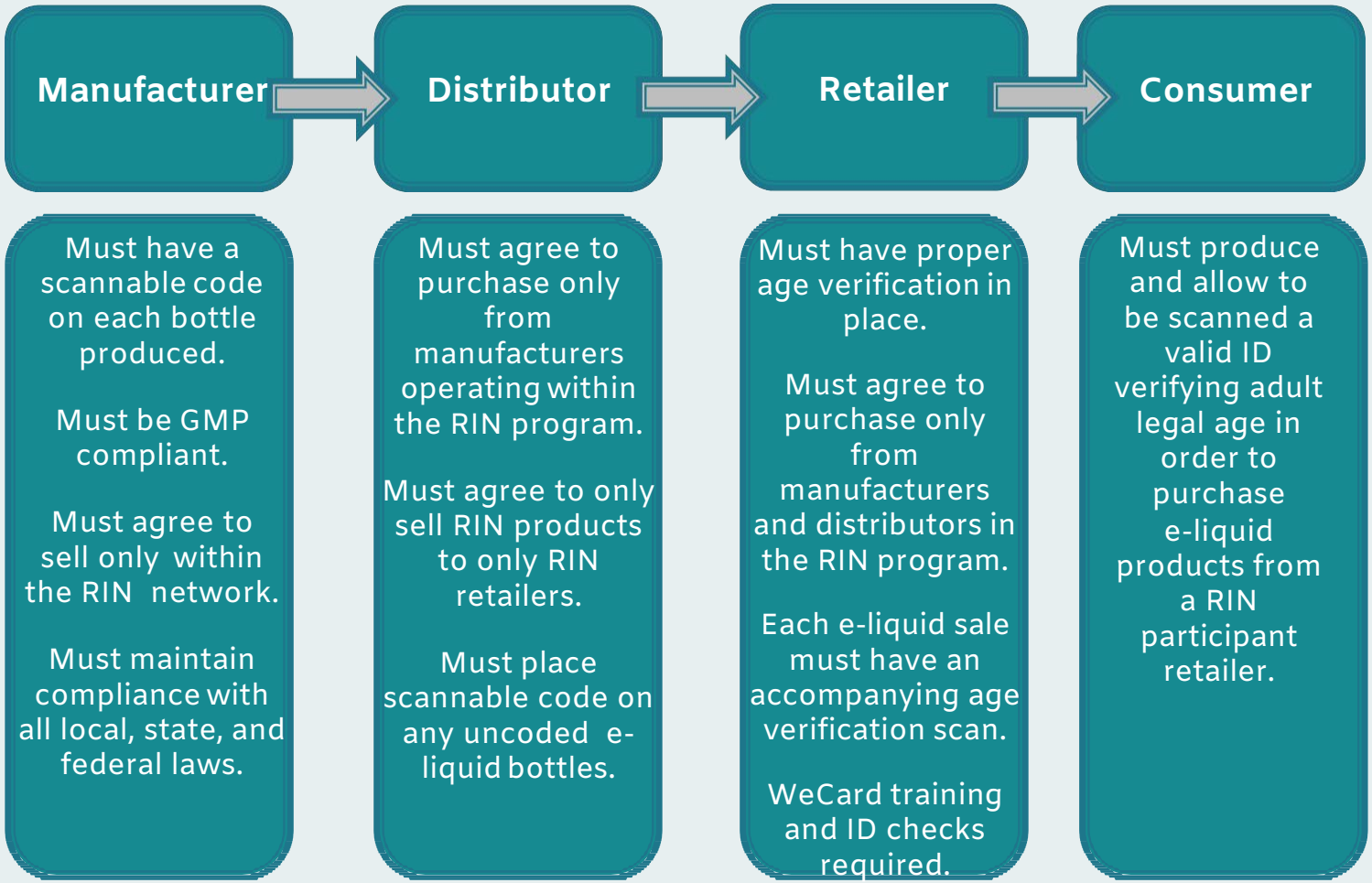
Key Components of the RIN Program

- **Controlled Distribution Network** - Retail participants commit to selling products purchased from manufacturers and distributors also participating in the program, ensuring a closed-loop system of control.
- **Robust Age Verification** - Includes requirements for adult-only retail establishments and eCommerce platforms to implement third-party age verification through an approved platform. (i.e., Intellicheck, Veritad, BlueCheck, etc.)
- **Upgraded Product Tracking Measures** - Partnership with TraceVerify or RFID tag/QR Code tools to link product manufacturing history to purchaser ID.
- **Routine Monitoring and Data Collection** - SFATA will send out surveys to its retail and distributor participants on behalf of its manufacturer participants to streamline processes and alleviate the burdens on all. SFATA will compile data and present it to manufacturers for submission to FDA.
- **Enhanced Enforcement** - Through program-related corrective actions and penalties, and data-sharing with law enforcement and regulatory authorities.
- **Accountability** - SFATA compliance officer will work with SFATA's Oversight Committee to ensure participating members operate within the parameters of the RIN Program.

Understanding the RIN Supply Chain

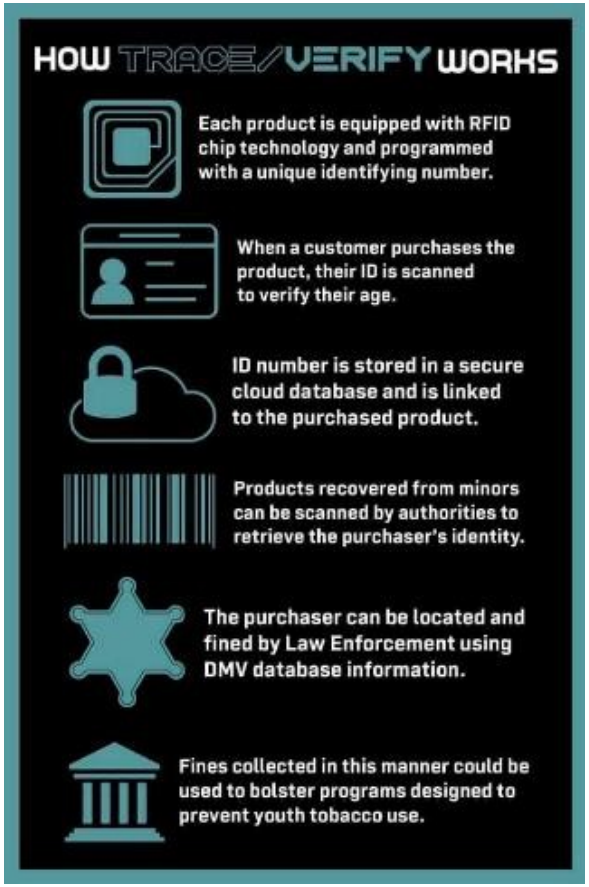
Suppliers	Typically mid- to large-sized businesses. Suppliers provide flavoring, nicotine, base components (i.e. glycerin, propylene glycol), bottles, labels, and packaging. Suppliers do not singularly service the vapor industry.
Manufacturers	RIN participant manufacturers range in size from small companies to large businesses that produce bottles of e-liquid to service the open-system market.
Distributors	RIN participant distributors range in size from small companies to large businesses distributing vapor products to retailers in the vapor space that are adult-only establishments.
Retailers	RIN participant retailers are predominantly small to mid-sized businesses servicing their local communities. They are primarily specialty vapor stores and operate as adult-only establishments.
Consumers	Consumers of RIN participant manufacturers, distributors, and retailers mainly purchase open-vapor e-liquid products. The overwhelming majority are former users of combustible tobacco products and rely on flavored liquids.

The RIN Controlled Distribution Network



Basic RIN Program Tools

Trace/Verify
Most important tool for manufacturers/distributors



WeCard
Most important tool for retailers

More RIN Program Tools

- Intellicheck | TokenWorks – Age authentication / age verification platform**
- TraceVerify – E-liquid track and trace tool***
- WeCard – Training tool***
- RIN Proposal – PMTA submission tool available to RIN participants who have sent in applications to FDA as an add-on to youth prevention procedures. SFATA has urged FDA/CTP to accept RIN as a valid youth prevention program.
- Age Verification Policy Templates – Will be made available to retail and eCommerce RIN participants.
- Education and Training – Will be offered to all RIN participants on an on-going basis on the various pieces of the program.

**Discount available as SFATA member benefit
***Specific allotment included with RIN membership – additional costs at business owners' expense.

Post-Market Surveillance

- SFATA will distribute streamlined surveys to distributors and retailers on behalf of manufacturers, minimizing the burdens on each. This will eliminate retailers being bogged down with demands from manufacturers requiring different data sets at different times and conversely eliminate the need for manufacturers to send out data to each of its retailers and chase down collection.

- SFATA will collect completed surveys, analyze the data, and produce a report for each RIN participant manufacturer.

- RIN manufacturers submit post-market surveillance report with any additional data to FDA/CTP.

- FDA/CTP receives data in a streamlined format from all RIN participants, saving both time and money.

Enforcement

SFATA believes RIN participants drastically reduce underage use of vapor products through our closed-loop system. SFATA believes the RIN program will increase the effectiveness of law enforcement and regulatory agencies by means of deterring straw-buyers and reining in bad actors.

Through TraceVerify and other RFID/QR Code track and trace platforms, the customer's age, driver's license number, and the state of issue will be permanently linked to the unique identifying number of the purchased vapor product and be stored in a secure cloud database. Law enforcement can access to cross-reference purchase data against DMV information.

This will identify the offending straw-buyer, or the employee who either did not scan the customer's ID or scanned the ID of an underage user. The technology will allow authorities to levy appropriate enforcement actions and allow SFATA to take corrective measures with non-compliant participants through RIN's Oversight Committee.

RIN – Join Now!

If you've read this far, you must be considering all the ways the RIN program can benefit your business.

The vapor industry, as we know it, has changed and will continue to change. If you are serious about being a part of the industry's future, we urge you to JOIN NOW!!

CTP has stated it has received hundreds of PMTA submissions. Waiting, in this situation, won't work. There are just too many moving parts, and we need time to get you ready for what's next – post-market surveillance. Potentially before that, you may be asked for a more robust youth prevention program and will have a limited time to reply. So why wait, when you can prepare yours TODAY?

We love talking about the RIN program, so if you have questions, we encourage you to bring them to us!

Email: info@sfata.org or call us at 202-251-1661.

We hope to see you join SFATA and the RIN program SOON!

References

1. National Institute of Health/ (2020). The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking Among Regular Adult Vapers From Canada and the United States: Findings From the 2018 ITC Four Country Smoking and Vaping Survey. Retrieved from https://pubmed.ncbi.nlm.nih.gov/32449933/
2. Premarket Tobacco Product Applications and Recordkeeping Requirements. Docket No. FDA-2019-N-2854 Fed. Reg. Proposed September 25, 2019. Section 6b. Labelling and Market Plans.
3. Premarket Tobacco Product Applications and Recordkeeping Requirements. Docket No. FDA-2019-N-2854 Fed. Reg. Proposed September 25, 2019. Section 6b: Labelling and Market Plans.


SAVING VAPING EVERY DAY
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