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## **Vaping Analytical Science Initiative (VASI)**

### **Background**

Despite marketplace acceptance, relatively little work has been done to characterize the vapor from vape devices. To date, the majority of vapor from vape device research has focused on characterizing the solutions, which are ultimately vaporized for the end user to inhale. Various methods have been developed for the analysis of electronic cigarette solutions and vapor to determine nicotine content and impurity profiles, including gas chromatography–flame ionization detector (GC-FID) methods (using both helium and hydrogen carrier gas), a straightforward GC mass spectrometry (GC-MS) method developed for the determination of impurities in vape device liquids. None of these methodologies have been validated by a third party. Moreover, there is no consensus and no apparent mechanism to develop consensus.

AOAC has been involved with cannabis analytical science for more than two years developing *Standard Method Performance Requirements* (SMPRs) and reviewing methods for cannabinoids in plants, extracts and edibles. This experience has given AOAC insight and connections to this emerging science community. Vaping is an allied community as vaping products overlap cannabis products. In addition to cannabis vaping products, there are also two additional distinct major vaping product categories; nicotine vaping products and flavored vaping products colloquially known as “e-juice” that do not contain cannabis or nicotine.

AOAC is ideally positioned to provide a platform for the vaping science community to develop trusted analytical standards and methods to address the most pressing challenges to ensure vaping safety. Success in these endeavors, *i.e.* the adoption of *Official Methods of Analysis*, will form the basis for a comprehensive program that will encompass proficiency testing, reference material development, and education and training.

### **Proposal**

AOAC INTERNATIONAL is proposing the formation of a funded project to be known as the *Vaping Analytical Science Initiative* (VASI). It is envisioned that through VASI and the leadership of AOAC INTERNATIONAL, government; academia; contract laboratories; technology providers; industry; and, allied associations will join forces as an analytical community to:

- 1) Identify, discuss and prioritize analytical challenges;
- 2) Develop standards to address prioritized needs;
- 3) Conduct method conformity assessments resulting in *Official Methods of Analysis* (OMA);
- 4) Identify reference material needs,

- 5) Develop criteria for a proficiency testing program; and
- 6) Develop educational and training materials focused on the needs of laboratories analyzing vaping materials.

AOAC is further proposing that the initial focus of VASI be on e-juices and heated vapors. Vape devices create vapor made of fine and ultrafine particles of particulate matter, which have been found to contain propylene glycol, glycerin, nicotine, flavors, small amounts of toxicants, carcinogens, and heavy metals, as well as metal nanoparticles, and other substances. Potential areas of interest for the development of SMPRs includes accuracy in label claim potency; and/or public safety issues such as detection and measurement of propylene glycol, glycerin, nicotine, flavors, toxicants, carcinogens, heavy metals, and metal nanoparticles for both e-juice and resulting heated vapors. AOAC will host a Thought Leader Dialogue to help focus the analytical and public health challenges.

## **AOAC is Seeking Your Support**

VASI will be guided by an Advisory Panel (AP) comprised of funding organizations. The AP will identify priorities and working group objectives. The AP will meet quarterly to review progress and consider additional objectives as a result of working group accomplishments.

Advisory Panel members will receive discounts on method submissions and consulting fees.

**To become an AP member, AOAC is asking interested organizations for a contribution of \$10,000.** Other levels of contributions will be considered as well<sup>1</sup>.

VASI activities will commence once financial support has met or surpassed \$80,000<sup>2</sup>. This level of funding supports the following:

- One Thought Leader Dialogue of subject matter experts (SMEs) and supporters to identify priorities; and, identify and recruit additional SMEs for one working group,
- One working group to draft consensus documentation (SMPRs),
- Publication of approved consensus documents,
- At least one (1) annual in-person program meeting,
- Working group meetings and subgroup meetings (both in-person and web conference),
- Travel costs for no more than three (3) invited key stakeholders/experts needed to complete the work.

### **Initial Project Goals**

- Form an Advisory Panel comprised of funding organizations.
- Develop a series of SMPRs. The number of SMPRs will depend on funding and direction from the Advisory Panel.
- Call for methods for each of the completed SMPRs.
- Creation of one or more Expert Review Panels to review and evaluate candidate methods submitted in response to SMPRs and Call for Methods.

### **Timetable**

- September to December 2020: Organize an Advisory Panel consisting of funding organizations.
- January 2021: Advisory Panel or town hall meeting to determine priorities.
- February 2021: Identify renowned subject matter experts to serve as working group chairs and in the working groups.
- March 2021: Working group chairs will present a 'launch presentation' to the stakeholders.

- April to August 2021: The working groups will meet by teleconferences to draft SMPRs, recommendations, and guidance documents.
- September 2021: The working group chairs will present draft SMPRs for review and approval during the 2021 AOAC Annual Meeting.
- Issue Call for Methods in October 2021.
- March 2022: AOAC Expert Review Panel to review methods

## Benefits for You

**If you are a method developer:** AOAC will develop standards for vaping methods that you can use to develop your methods and will be used by AOAC Expert Review Panels to evaluate candidate methods. A specially designed AOAC VASI logo will be available for Pioneer Level Advisory Panel Members use.

**If you are an analytical laboratory, regulator, or manufacturer:** you can participate in development of standards for analytical methods for vaping products. These standards will then be used by method developers to develop analytical methods, and by AOAC for method evaluation so that *Official Methods of Analysis* best meet your analytical needs. A specially designed AOAC VASI logo will be available for Pioneer Level Advisory Panel Members use.

**For all:** This project will produce consensus performance standards and *Official Methods of Analysis* for stakeholders. Such trusted methods will provide reliable data for the effective compliance-driven quality control of vaping products.

## Deadline

The deadline for this initial pledge or contribution is December 31, 2020.

## Contact Information

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<sup>1</sup>AOAC INTERNATIONAL will consider a multi-tiered funding option to avoid any unintended barrier to the ultimate success of this project and to encourage as many stakeholders to get involved as possible.

<sup>2</sup>This price only reflects the cost for supporting one Thought Leader Dialogue, one working group and the associated publication costs. Additional working groups will require greater financial support. Costs not covered include any needed laboratory work, establishment of one or more subsequent Official Methods expert review panels and any candidate method activities. Final costs will be confirmed in a document of understanding between AOAC INTERNATIONAL and all participating organizations.