

China Is Drafting First E-Cigarette Standard



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"Electronic cigarettes may soon become much more widely available in the world's largest tobacco market: The People's Republic of China. With over 300 million smokers, China has the world's largest smoking population - which directly results in approximately 1 million deaths annually." ^[1] While the **global e-cigarette market** has experienced rapid growth over the last decade, **reduced-harm products** have only recently started becoming popular domestically, despite the fact that the modern e-cigarette was invented in China, and the vast majority of e-cigarette devices exported around the world are manufactured in Shenzhen.

But times are changing, as the U.S. clamps down on the e-cigarette industry and requires robust premarket applications, China has taken a major step toward permitting the sale of regulated e-cigarettes by publishing a draft national standard (GB) on "electronic cigarettes." The Standard was notified to the World Trade Organization (WTO) on May 1, 2019.^[2]

As its name suggests, the Standard applies to electronic cigarettes, referring to "a system consisting of electronic cigarette device and e-liquid that produce inhalable aerosol." Other novel tobacco products outside this definition are not captured by this Standard.

The comprehensive new Standard consists of the following seven chapters:

1. Scope
2. Reference standards
3. Terms and definitions
4. Technical requirements
5. Testing methods
6. Packaging, labeling and instruction manual
7. Storage and transportation

The Standard also contains sixteen appendices, including those on the methods for the determination of various substances in the e-liquid, sample labels of e-cigarette device and e-liquid, etc. Particularly, Appendix B provides a positive list of 119 additives that are permitted for use in e-liquid. The use of non-listed additives will be subject to prior safety assessment, with considerations on the edible safety, inhalation safety, stability, addiction, etc. of a substance. We expect that more details about the safety assessment on non-listed substances will be provided in separate regulations. Certain additives also are explicitly prohibited from being used in e-liquid, such as substances purely for coloring purposes, carcinogenic, mutagenic, reproductive toxic and respiratory toxic substances, 2,3-butanedione, etc.

Other notable technical requirements under the draft Standard include:

For e-cigarette device:

§ Mechanic and physical performance, such as sealing, maximum surface temperature, etc.;

§ Electrical performance, such as input/output power, batteries, etc.; and

§ Chemical performance; for example, materials used for components in contact with the mouth or e-liquid must comply with the corresponding food packaging standards of China, such as GB 4806.7 on plastics articles, GB 9685 on food packaging additives, etc.

For e-liquid:

§ Purity and concentration limits for nicotine;

§ Requirements for base liquid, including glycerin, propylene glycol and water;

§ Limits for impurities and contaminants; and

§ Requirements for material in contact with e-liquid; they must comply with the corresponding food packaging standards.

For emissions:

§ Stability of aerosol and nicotine emissions; and

§ Limits for carbonyl compounds and heavy metals.

The **new Chinese Standard on e-cigarettes** will be published by the State Administration for Market Regulation (SAMR) and the Standardization Administration of China (SAC), but the agency responsible for drafting and maintaining the Standard is the State Tobacco Monopoly Administration. It is unclear when this Standard will be finalized and published; Chinese authorities may release the Standard later this year. Nevertheless, the new Standard will have a significant impact on the regulatory landscape of the manufacturing, sales and import of e-cigarette products in China. Industry should be mindful of its development and make sure that the e-cigarette products manufactured or imported in China entirely comply with the detailed requirements under the new Standard.

[1] See [China Smoking Deaths Annually](#).

[2] See [China Draft National Standard for E-Cigarettes to WTO](#)

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