China Publishes Final GB Standard on E-Cigarettes: The Basis for Product Compliance

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Since we reported in December 2021 on some significant developments in China’s regulation of e-cigarettes (including the draft national standard on e-cigarettes) as well as in March 2022 on the finalized Management Rules for E-Cigarettes, China’s State Tobacco Monopoly Administration (STMA), also referred to as China National Tobacco Corporation (CNTC), has not only released the national Standard GB 41700-2022 on Electronic Cigarettes but also published further regulations detailing the procedure and requirements for licensing, technical review, etc. In the coming weeks, we will publish a series of articles summarizing these new regulations. This article will first focus on GB 41700-2022.

We should note that, according to the Management Rules for E-cigarettes, e-cigarettes for export only are not necessarily required to comply with GB 41700-2022; rather, they must comply with the destination country’s laws, regulations, and standards. When the destination country has no relevant laws or standards, e-cigarettes only for export must comply with China’s laws and standards, which we understand will include GB 41700-2022.

GB 41700-2022 was published on April 8, 2022, and will take effect on October 1, 2022. As we previously reported, the first draft Standard was notified to the World Trade Organization (WTO) in 2019. At that time, China had not officially placed e-cigarettes under the state tobacco monopoly. Later, in November 2021, around the same time of the publication of the amended Implementing Regulation of the Tobacco Monopoly Law (which places e-cigarettes under tobacco monopoly in China) and the draft Management Rules, STMA published a new draft Standard on e-cigarettes for comment. In March 2022, STMA further amended the draft Standard for another round of public comment. The current GB 41700-2022 is largely consistent with the March 2022 draft, and its structure is as follows:

- Section 1 – Scope
- Section 2 – Referenced standards
We summarize the major requirements below.

**Definitions**

“Electronic cigarette” is defined as an electronic delivery system used to generate aerosols for human smoking, excluding rolled cigarettes. We note that, in the 2021 draft, the electronic cigarette is used to generate “nicotine-containing” aerosols. The Chinese government explained that the removal of the “nicotine-containing” language here is to include e-cigarettes that do not contain nicotine in the definition of e-cigarettes. At the same time, the current Standard also adds that e-atomization materials must contain nicotine, which, as explained by the Chinese government, prohibits the sales of e-cigarettes that do not contain nicotine.[1] Such amendments and the accompanying government explanation are significant, as they seem to suggest that e-cigarettes without nicotine also are regulated as e-cigarettes in China and are prohibited from sales.

“E-atomization materials” refer to the mixture and auxiliary substances that can be partly or totally atomized by the electronic device into absorbable aerosols. E-liquids are e-atomization materials in the liquid state. Consistent with industry practice, we will use the term “e-liquids” for the remainder of the article.

**Nicotine in e-liquids**

As required in the previous drafts, the Standard states that e-liquids must contain nicotine, and such nicotine must be extracted from tobacco, with a purity of no less than 99%. The Standard further requires that the nicotine concentration in e-liquids must be no more than 20 mg/g, and the total nicotine content must be no more than 200 mg. On the other hand, nicotine emission per puff must be no more than 0.2 mg.

**Additives in e-liquids**

The Standard requires that additives permitted for use in e-liquids and the maximum use levels must follow Appendix A, which lists 101 substances. In the 2021 draft, this list is a part of Appendix B and contains 122 substances. The Standard also provides that the use of other additives must evaluate their toxicological characteristics and use safety risks, and confirm that such use will not increase risks to the health of the user. The scope of evaluation includes, but is not limited to, food safety,
absorption safety, and safety under the use conditions. Following this provision, it seems that the use of additives not listed in Appendix A is possible, but it is not entirely clear how the evaluation should be performed. In the meantime, the following substances are prohibited from being used as additives: a) substances with carcinogenicity, mutagenicity, genotoxicity, or respiratory system toxicity; b) additives and stimulants related to energy and vitality; c) substances that may lead to wrongful consumer perception of benefiting health or reducing harms; and d) substances solely for coloring purposes.

**Restricted substances**

Like the previous two drafts, the current Standard also imposes restrictions on “electronic cigarette materials,” i.e., materials, not including e-liquids, used for the manufacture of e-cigarettes. However, while the previous two drafts generally require that materials in contact with the mouth, e-liquids, and e-cigarette emissions must meet the requirements for food-contact materials. The current Standard more specifically requires that these materials comply with GB 4806.1 (General Safety Standard) as well as the Materials Standards from GB 4806.3 to GB 4806.11. These Materials Standards cover specific food-contact materials including plastics, paper, metal, etc. This may bring about compliance issues if in the future China publishes new Materials Standards, such as those on composite materials, adhesives, etc.

On the other hand, for those materials not in contact with the mouth, e-liquids, or e-cigarette emissions, the previous drafts and the current Standard seem to take different approaches. In the 2021 draft, it is required that such materials must comply with the limits on restricted substances in electrical and electronic products and provides a list of exceptions in Appendix A. In the March 2022 draft, Appendix A is replaced by the positive list of additives (see above), and it is only generally required that such materials must comply with the relevant standards and regulations on electrical and electronic products. The current Standard also removes the original Appendix A but more specifically requires that such materials must comply with the limits on restricted substances in homogeneous materials in GB/T 26572. In the currently effective GB/T 26572-2011, the standard on “requirements for concentration limits for certain restricted substances in electrical and electronic products,” the limits on restricted substances in homogeneous materials are: lead, mercury, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers (must not exceed 0.1%), and cadmium (must not exceed 0.01%).

**Flavors**

As part of the design requirements, the Standard requires that e-liquids are not allowed to be inducive to minors and are not allowed to have the product present characteristic flavors other than tobacco. This language is not found in the 2021 draft but seems to be added for consistency with the Management Rules, which contain the same requirement. This may lead to uncertainty in practice, especially when various flavoring substances are permitted additives in Appendix A.

The Standard contains various other requirements, for example, the e-cigarette device and the cartridge must have a closed structure preventing “artificial filling,” which essentially prohibits refillable e-cigarettes. The Standard also provides specifications on levels of impurities in e-liquids and carbonyl compounds in emissions.

**FOOTNOTES**

[1] See Answers to Questions Related to the Management Rules for Electronic Cigarettes and the National Standard on Electronic Cigarettes, STMA,