

# The Path of Legalization of E-Cigarette Supervision

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**Abstract:** In recent years, although people have paid more and more attention to the negative effects of e-cigarettes on people's health, and China has gradually strengthened the supervision of e-cigarettes in order to protect people, especially minors, from the infringement of e-cigarettes, the legalization of e-cigarettes supervision cannot be achieved overnight, and there are still some problems such as the lack of national industry standards, disputes over regulatory subjects, unclear classification management, etc. Therefore, China should speed up the introduction of industry standards, determine the regulatory body with the aim of protecting national health, especially the rights and interests of minors, scientifically define the categories of e-cigarettes and formulate different regulatory measures, so as to safeguard national health while taking into account the healthy development of the e-cigarette industry and stimulate the innovative spirit of private enterprises.

**Key words:** e-cigarettes; supervision; legalization  
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E-cigarette, with its global popularity and the expansion of the market size, is also facing increasingly prominent hazards. The World Health Organization clearly pointed out in the *Global Tobacco Epidemic Report in 2019* that e-cigarettes are harmful and should be managed. On May 26, 2021, the National Health Commission of the People's Republic of China issued the *Report on Health Hazards of Smoking in China 2020* in Beijing, in which a chapter on the health hazards of e-cigarettes was added compared with the old report issued by the former Ministry of Health in 2012, pointing out that "there is sufficient evidence that e-cigarettes are unsafe".<sup>1</sup> On June 1, 2021, the newly revised *Law of the People's Republic of China on the Protection of Minors* came into force, explicitly proposing, for the first time in the form of law, the regulation of e-cigarettes to prevent minors from being infringed upon. Article 17 of

the Law stipulates that parents or other guardians of minors shall not allow or instigate minors to smoke, including e-cigarettes. Article 59 stipulates that no cigarette shops shall be set up around the school, and the sale of e-cigarettes to minors shall be prohibited. Signs prohibiting the sale shall be set in prominent positions, and no one shall smoke in public places where minors are concentrated. From the perspective of protecting national health, especially the physical and mental health of minors, it is imperative to strictly supervise the e-cigarette industry from the long-term healthy development of the industry, and the establishment of supervision mode and the formulation of supervision rules need to be put on the agenda.

**THE DEFINITION, CLASSIFICATION AND DEVELOPMENT PROCESS OF E-CIGARETTES**

E-cigarette is a device shaped like a traditional cigarette that delivers a atomized chemical mixture (usually a hydraulic mixture, mostly containing nicotine) to the respiratory system by electronic heating. E-cigarettes are mainly divided into three categories: first, heat not burn e-cigarettes for tobacco leaves (with batteries inside, which is different from traditional cigarettes); second, non-combustible electronic atomizers containing nicotine; and third, non-combustible electronic atomizers without nicotine.<sup>2</sup>

E-cigarette was designed to help smokers control and quit smoking. According to the evidence updated by the British Ministry of Public Health in 2021, e-cigarettes have become the first choice for those who try to quit smoking in Britain in 2020. This is also the case for consumers in China in their early understanding of e-cigarette that it is a healthy product that is "free of second-hand smoke" and "free of carcinogens such as tar", helping people to quit smoking. These "labels" are constantly promoted and strengthened by e-cigarette practitioners, and at the same time promote the rapid development of e-cigarettes. From 2013 to 2018, China's e-cigarette market continued to grow in size, with the growth rate always maintained at more than 20%, to 8.33 billion yuan in 2020, is expected to exceed 10 billion yuan in 2021.<sup>3</sup> The fast-growing market scale is not effectively supervised by relevant laws and regulations. Compared with traditional cigarettes, the advantages of online and offline sales channels and low taxes have made e-cigarettes gain excessive attention and pursuit from capital and financial institutions for a long time in the past, and become a profiteering industry, which has entered a disorderly and barbaric development trend. Up to 2019, the number of people aged 15 and above using e-cigarettes in China was about 10 million. The majority of people using e-cigarettes were young people, with the 15-24 year-old group having the highest usage rate. Statistics from the China Center for Disease Control show that in 2019, 3.0% of high school students and 2.7% of junior high school students in China used e-cigarettes.<sup>4</sup> At the same time, the negative effects of e-cigarettes are attracting more and more attention from relevant departments and experts. According to the *Report on Health Hazards of Smoking in China 2020* released by the National Health Commission of the

People's Republic of China, e-tobacco tar contains toxic substances that have a strong stimulating effect on the respiratory system, and is a highly carcinogenic substance, or can aggravate respiratory tract inflammation, and may form "popcorn lung" in severe cases. Nicotine-containing e-cigarettes are easy to make users addicted to them and have adverse effects on the development of fetuses and teenagers, leading to learning disorders and anxiety disorders. On July 27, 2021, WHO released the *WHO Global Tobacco Epidemic Report 2021*, in which new data about "electronic nicotine delivery system" (e.g., e-cigarette) was presented for the first time. The report pointed out that enterprises of these products often sell to children and adolescents using thousands of attractive scents and misleading statements about products, and children who use these products are three times more likely to use tobacco products in the future than those who do not use them.<sup>5</sup> These shocking research conclusions and data make people have to re-examine e-cigarettes, so it is imperative and urgent to supervise them through legislation.

## STATUS QUO OF LEGISLATION ON SUPERVISION OF E-CIGARETTES

As early as 2006, when the development of e-cigarettes was booming, there were discussions on the attributes and supervision methods of e-cigarettes. However, limited by the law, there was no clear legal definition of e-cigarette as a new product. At that time, the State Tobacco Monopoly Bureau, the State Administration of Industry and Commerce and State Administration of Work Safety all thought that e-cigarette did not fall in their own regulatory scope,<sup>6</sup> because it was neither a tobacco product, a drug nor a medical device, so it could only be regarded as a general product and was regulated by the *Product Quality Law*, *Civil Code-Tort Liability* and *Consumer Rights Protection Law* in terms of quality. Nevertheless, for emerging products such as e-cigarettes that are directly inhaled by the human body and may pose a threat to health, and for which scientific research is insufficient, it is undoubtedly feeble to regulate them only through the general provisions on product quality.

With the disordered development of e-cigarette industry and its negative impact on the physical and mental health of users, more and more people

are paying attention to it. Particularly, the proportion of minors using e-cigarette increases year by year. Therefore, relevant departments are actively introducing some rules and regulations in recent years in order to reduce the impact of e-cigarette on minors as much as possible. For example, in August 2018, the State Administration of Market Supervision and the State Tobacco Monopoly Bureau jointly issued the *Notice on Prohibiting the Sale of E-cigarettes to Minors*, which curbs the sale of e-cigarettes to minors in physical stores. In November 2019, the above-mentioned two institutions issued the *Notice on Further Protecting Minors from E-cigarettes*, targeting the operators' selling e-cigarettes to minors through online channels. On March 22, 2021, the Ministry of Industry and Information Technology issued the *Decision on Amending the "Regulations of the People's Republic of China on the Implementation of the Tobacco Monopoly Law"* to solicit public opinions, proposing that "new types of tobacco products such as e-cigarettes shall be implemented in reference to the relevant provisions on cigarettes in these regulations." Industry analysis indicated that e-cigarettes will face strict supervision in production, sales, publicity and taxation. On June 1, 2021, the *Law of the People's Republic of China on the Protection of Minors* came into force, which explicitly proposed to regulate e-cigarettes in the form of laws for the first time. Subsequently, the State Administration of Market Supervision and the State Tobacco Monopoly Administration issued the *Special Action Plan for Protecting Minors from Tobacco and Protecting Their Growth*, which defined the work objectives in stages, continuously strengthened the supervision of the e-cigarette market to effectively protect the healthy growth of minors. However, most of the above laws, regulations and rules restrict e-cigarettes from the perspective of protecting minors, and no overall industry regulation has been formed. In addition, in the *Exposure Draft* of the Ministry of Industry and Information Technology, the implementation of e-cigarettes with reference to cigarette regulations is also controversial.

## DIFFICULTIES FACED BY THE LEGALIZATION OF E-CIGARETTE SUPERVISION AND COUNTERMEASURES

**Imminent introduction of the standard due to**

### **the lack of e-cigarette industry standards**

Up to June 1, 2021, there is only one relevant industry standard for "e-cigarettes" found at csres.com, which is the standard for "general technical requirements for e-cigarette aerosol products" issued by the Shenzhen Municipal Market Supervision and Administration Bureau. Currently, the state has not yet issued relevant industry standards. In 2019, the national standard plans *E-cigarette* and *Gas Chromatography for Determination of Nicotine, Propylene Glycol and Glycerol in E-cigarette Liquid* were reported and implemented by TC144 (National Tobacco Standardization Technical Committee), under the supervision of the State Tobacco Monopoly Bureau, which is currently in the "under review" stage and has not been released yet. According to the plans, the standards to be issued in the future will impose mandatory regulations on the tobacco juice (with emphasis on nicotine, i.e. the composition and content of nicotine), appliances, releases, packaging marks, storage and transportation of e-cigarettes, so as to ensure that e-cigarettes do not pose a direct threat to the health and safety of consumers.<sup>7</sup> The standard will also be an important basis for the rule of law to regulate the e-cigarette industry. The relevant departments of the state should speed up the development of standards, to provide a basis for the classification of e-cigarettes, to determine the extent of harm to minors, and on this basis, to strengthen the advertising supervision of all kinds of products and make people have a correct understanding of different types of e-cigarettes through a wide range of knowledge popularization.

### **Relevant disputes over the subject of supervision**

On March 22, 2021, the Ministry of Industry and Information Technology issued the *Draft for Comments* which proposed that "e-cigarettes and other new tobacco products shall be implemented with reference to the relevant provisions on cigarettes in these Regulations". Therefore, it seems logical to put e-cigarettes under the supervision of the State Administration of Tobacco Monopoly, which is the regulatory authority of China's traditional cigarettes. However, there are also different opinions that the State Administration of Tobacco Monopoly is both a stakeholder in tobacco production and a supervisor of the tobacco industry, which is in violation of the

principle of the rule of law. It is suggested that the supervision of e-cigarettes should be handed over to the State Department of Health, the food and drug regulatory authorities or the Market Supervision and Administration.<sup>8</sup>

The following aspects are considered for the determination of supervision subject

1. E-cigarette monitoring should balance national health, fiscal revenue and industrial development.

The change of e-cigarette supervision mode is bound to be a process of interest rebalancing. The consideration of national health, especially the physical and mental health of minors, is the starting point and the end result of the legalization of e-cigarette supervision, which is the most important among many interest evaluations. It is the basic requirement of industrial development not to simply pursue the rapid development of the industry and high economic profits and financial income at the expense of national health. After several years of rapid development, the e-cigarette industry has formed a pattern of "Made in China and consumed globally". Statistics show that 90% of the world's e-cigarette supply comes from China, which maintains a strong position in the world.<sup>9</sup> The development of the industry is related to the micro interests of many private enterprises, and the innovative spirit and international ability of private enterprises should be respected. In addition, as China's e-cigarettes are mainly export-oriented, the determination of the nature of e-cigarettes and the determination of the regulatory authorities will also affect the export of e-cigarettes and the foreign market's policy towards China's e-cigarettes. If e-cigarettes are classified as tobacco and supervised by the State Tobacco Monopoly Administration, they will fall within the framework of China's tobacco monopoly system. However, China's tobacco market will not be open to foreign capital, and foreign tobacco markets will not be open to China's capital according to the principle of trade reciprocity, thus the legitimacy of e-cigarette export trade becomes a problem. Tax collection, even high taxes, is an important measure taken by many countries in monitoring e-cigarettes, because tax increase in the e-cigarette industry is bound to increase the fiscal revenue, but it will have an impact on the retail price of e-cigarettes, consumer-related expenses and the profits of industry practitioners. Therefore, in the

design of regulatory rules, it is necessary to legislate scientifically, listen to the opinions and suggestions of various stakeholders, and regulate in a balanced way.

2. Drawing lessons from international practices

According to data from Euro monitor International, a global consultancy, the top two countries in global sales of e-cigarettes in 2019 are the United States and the United Kingdom, which also have a long history of e-cigarette supervision. In 2009, the US Congress officially authorized FDA (Food and Drug Administration) to supervise tobacco products including e-cigarettes. In 2013, the Public Health England (PHE) was established, and it also began to supervise tobacco products for the purpose of health improvement. In Australia, e-cigarettes are supervised by the Drug Administration.<sup>10</sup> At the national level, the regulatory model in most countries makes it customary for third-party regulation.

3. Starting from the key protection of the interests of minors

The newly enacted *Law on the Protection of Minors* has already put forward clear regulations on e-cigarettes, and how to effectively prevent minors from being infringed by e-cigarettes. When determining the subject of supervision, factors such as the authority and functions of each agency, whether there is conflict of interests with the purpose of protection, etc. need to be considered.

In view of the above considerations, combined with the contents of the *Exposure Draft*, it is necessary to set up a comprehensive management institution which mainly focuses on the General Administration of Tobacco Monopoly and gathers the General Administration of Tobacco Monopoly, drug supervision and administration institutions, market supervision and administration institutions and even youth rights and interests protection institutions to supervise e-cigarettes.

### **Consideration on the classification supervision of e-cigarettes**

E-cigarettes can be divided into different categories based on different standards. For example, it is divided into heat not burning e-cigarette (abbreviated as HNB) and atomizer e-cigarette according to the principle of smoke discharge, CBD e-cigarette, nicotine e-cigarette and nicotine-free e-cigarette according to the category of tobacco tar, simple cigarette and

complicated cigarette according to the size of the smoke, disposable cigarette (e-cigarette that cannot be recharged and reused, and will be discarded when the tobacco tar is exhausted), disposable cartridge e-cigarette (the cartridge is separated from the stem, and the stem has a battery for recharging and reuse, and cartridge can be changed without changing the stem after the cartridge is used up), Squonk Mod (recycled, the cartridge has a long service life, and the tobacco tar in the cartridge can be repeatedly injected for 3-6 times to continue to be used), and Cigalike (the size and appearance of the cigarettes are the same as those of real cigarettes, and the bright end of the e-cigarette lamp has the same effect as a cigarette ash head when smoking) and non-Cigalike (in various shapes, can generate smoke, but the shapes are not constrained to cigarettes), and the like.<sup>11</sup>

From the purpose of legalization of e-cigarette supervision, the foothold is to protect the national health, especially the health and safety of the national minor groups. Therefore, among many classifications, the most significant legislative reference is to consider the impact of e-cigarette use on people's health. The nicotine content in tobacco oil is an important index. E-cigarettes with or without nicotine should be subject to different regulatory rules. Even e-cigarettes containing nicotine should be compared with traditional cigarettes to determine specific parameters, and be supervised by comparison with cigarettes.

Judging from the legislative technique of the *Exposure Draft* issued by the Ministry of Industry and Information Technology, the essence of "reference" is "quasi-application" and the core of "reference application" as the quasi-application of legal rules lies in the consideration of similarity. As Wang Zejian said in his book *Study of Civil Law Theories and Cases (Volume 6)*, it is "to apply the provisions set for a certain matter to similar matters". In the *Exposure Draft*, e-cigarettes are required to be regulated with reference to cigarettes, because they are considered as "new tobacco products", which are similar to cigarettes, but this view is not accurate. In fact, the core of the e-cigarette device is an electronic atomizer, which is composed of a battery, a heating element, an atomizing liquid container, etc. It is an electronic product with the function equivalent to a pipe. Some of the liquids contain nicotine, others do not. Internationally, there is no precedent to

characterize nicotine-free aerosolized products as tobacco products. That is to say, as far as the e-cigarette is concerned, what is really similar to tobacco products such as cigarettes is "nicotine-containing atomized liquid". Electronic atomizers that do not contain nicotine are electronic products, which are different from "tobacco products" such as cigarettes. For electronic atomizers that do not contain nicotine, there is no room to apply the relevant monopoly regulations with reference to cigarettes.

Therefore, electronic atomizers without nicotine should be supervised separately, which has been adopted in many countries in the supervision of electronic cigarettes. For example, in Britain, nicotine-containing e-cigarettes are recognized as tobacco-related products, which are regulated by the *Tobacco and Related Products Regulations 2016* (TRPR), while nicotine-free e-cigarettes are regarded as consumer products, which are regulated by general consumer protection and product quality and safety regulations. E-cigarettes are also regulated separately in Australia. E-cigarettes without nicotine can be sold as ordinary consumer goods in retail stores as long as the manufacturer does not claim to be used for therapeutic purposes.

According to the provisions of China's *Tobacco Monopoly Law* and *Regulations for the Implementation of Tobacco Monopoly Law*, the state exercises monopoly management over the production, sale, import and export of tobacco monopoly products according to law, and implements a tobacco monopoly license system, which requires a license to engage in the production, wholesale and retail business of cigarettes and other tobacco products. If e-cigarettes are indiscriminately managed with reference to cigarettes and other tobacco products, and nicotine-free electronic atomizers are included in monopoly management, it will not only greatly affect the industrial chain of electronic atomizers in our country, increase the operating cost and supervision cost, but also may restrict the products in terms of export declaration and tariffs, and may also cause the entire industry to move abroad, which is not conducive to maintaining our competitive advantage in this field.

To sum up, it is imperative to supervise e-cigarettes and introduce industry standards for the protection of national health, especially the

physical and mental health of minors. The supervision of e-cigarettes cannot be carried out without distinguishing them from cigarettes. A relatively independent department should be set up based on the principle of differentiated supervision, the key to which is whether nicotine is a core ingredient. Nicotine-free electronic atomizers should be supervised as electronic products, with the emphasis on product quality and safety, while nicotine-containing atomized products can be considered as "new tobacco products" for supervision because they are similar to tobacco products, which can not only make up the regulatory gap, but also ensure the legitimate rights and interests of minors, and help to protect and promote the healthy development of China's emerging industries by means of the rule of law.

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