Regulations of the Health Risk Assessment Review of Designated Tobacco Products

Tobacco Hazards Prevention Act (hereinafter referred to as “this Act”) has been promulgated and amended under Presidential Order No. 11200010211 on February 15, 2023. Paragraph 1 of Article 7 of this Act stipulates that tobacco products designated by the central competent authority (hereinafter referred to as “the products”) shall be submitted by the manufacturers and/or importers to the central competent authority for application for the health risk assessment review and granted by the central competent authority before manufacturing or importing the products. Paragraph 2 of Article 7 of this Act stipulates that if new health risk(s) related to the tobacco products that have been declared to the central competent authority is/are discovered, the central competent authority may designate the tobacco products as the products that shall be submitted for application for the health risk assessment review within a specified period of time and order the recall of the products and suspension from manufacturing or importing the products within a specified period of time. If the products are not granted by the central competent authority under the health risk assessment review, the central competent authority shall order the recall or destruction of the products within a period of time and prohibit the manufacture and/or importation of the products. To provide legitimate grounds for the application and review, the regulations of the health risk assessment review are stipulated in pursuant to the authorization under Paragraph 3 of Article 7 of this Act, and the main points are as follows:

1) The source of law for these regulations (Article 1).
2) The obligor and time limit of and exemption from the submission of the products for application for the health risk assessment review (Article 2).
3) The application form, documents and data that shall be submitted by the manufacturers or importers of the products (Article 3).
4) The methods by which the central competent authority conducts health risk assessment review (Article 4).
5) The circumstances in which the application for the health risk assessment review shall be denied (Article 5).
6) The central competent authority may require the manufacturers and/or importers of the products which have been granted by the central competent authority under the health risk assessment review to submit post-market monitoring and control mechanisms (Article 6).
7) The amount of the fee for applying for the health risk assessment review is determined by the central competent authority (Article 7).
8) The products that are denied under the health risk assessment review shall not be submitted by the same applicant for application for the health risk assessment review within one year (Article 8).

9) The application form required in these Regulations shall be promulgated by the central competent authority (Article 9).

10) The central competent authority may authorize related professional institutions, agencies, legal persons or groups to execute the tasks in these Regulations (Article 10).

11) The effective date of these regulations (Article 11).

Regulations of the Health Risk Assessments Review of Designated Tobacco Products

Article 1

These Regulations are stipulated in accordance with the provisions of Paragraph 3 of Article 7 of Tobacco Hazards Prevention Act (hereinafter referred to as “this Act”).

Article 2

Designated tobacco products (hereinafter referred to as “the products”) shall be submitted by the manufacturers and/or importers (hereinafter referred to as “the applicants”) to the central competent authority for application for the health risk assessment review before manufacturing and/or importing the products or within the time limit specified by the central competent authority under Paragraph 2 of Article 7 of this Act. The products with research or test plans, not in commercialized packaging, not for sale, and their volume not exceeding the required volume for research or test are not subject to these regulations.

The application in the preceding Paragraph shall be submitted by the importers if the products are manufactured abroad.

Article 3

The application in the preceding Article shall be submitted with the application form promulgated by the central competent authority and the following documents and data of the products:

(1) Health risk research data which have been published or known to, or which should reasonably be known to, the applicants and health risk comparison results with other tobacco products;
(2) Data on raw materials, additives, and other relevant ingredients;
(3) Data on emissions;
(4) Data on the methods for testing the substances in Subparagraph 2 and 3 of this Paragraph;
(5) Processing methods;
(6) Research data on addiction of the users;
(7) Research data on that people younger than 20 years of age and first-time smokers are induced to use the products;
(8) Nicotine and tar yields in emissions of the minimum usage unit;
(9) Samples of the products and essential components and safety statements for use;
(10) Safety certification documents and/or data issued by certified laboratories in accordance with relevant national standards;
(11) Documents and/or data on the countries, the dates and the volumes that the products are granted for sale;
(12) Specific measures, implementation methods and the commitments for the monitoring and control mechanisms of tobacco hazards; and
(13) Other documents and/or data designated by the central competent authority.

The documents and/or data in the preceding Paragraph, except for figures, shall be submitted in Traditional Chinese, and annotated in English where necessary.

Where the documents and/or data required in Paragraph 1 are incomplete, the central competent authority shall order the applicants to supplement the documents and/or

data once and for all. If the documents and/or data are not supplemented within the specified time limit, the application shall be rejected.

International standards approved by the central competent authority may substitute for the national standards in Subparagraph 10 of Paragraph 1 before the national standards are promulgated.

Article 4

The central competent authority shall invite and assemble experts and scholars in public health, health policy, toxicology, and other relevant fields to conduct the health risk assessment review.

The review in the preceding Paragraph may refer to the relevant health risk assessment reviews and post-market monitoring and control mechanisms for the products in other countries, as well as other relevant regulatory measures.

Article 5

The application of the health risk assessment review of the products shall be denied if any one of the following circumstances occur:

(1) Insufficient data to prove that the health risks of the products are not higher than the cigarettes present in the domestic market;
(2) Any circumstance prohibited by this Act;
(3) Any emerging evidence which proves the obvious health impact; and
(4) Any circumstance in conflict with the announcements of the central competent authority.

Article 6

The central competent authority may require the applicant to implement and submit information of the following post-market monitoring and control mechanisms for the products that have been granted under the health risk assessment review:

(1) Ongoing or completed researches on the use of the products by consumers and the findings;
(2) Information on sales of the products and consumer complaints;
(3) Information on the use of the products of current and first-time smokers;
(4) Any change in manufacture process or composition of the products;
(5) Adverse event reporting, analysis, and response mechanisms;
(6) Newly discovered data on addiction;
(7) Information on adverse events of health occurring abroad; and
(8) Other necessary monitoring and control mechanisms.

If the applicants fail to comply with the provisions in the preceding Paragraph, the central competent authority shall order the applicants to take rectification within a specified period of time. If no rectification is taken within the time limit, the authorization for the products under the health risk assessment review shall be abolished.

Article 7.

The applicants of the health risk assessment review shall pay the fee; the amount of the fee shall be determined by the central competent authority.

Article 8

The products that are denied under the health risk assessment review shall not be submitted

by the same applicant for application for the health risk assessment review within one year since the arrival of the denial order.

Article 9

The application form required in these Regulations shall be promulgated by the central competent authority.

Article 10

The central competent authority may authorize related professional institutions, agencies, legal persons or groups to execute the tasks in these Regulations.

Article 11

The effective date of these Regulations shall be determined by the central competent authority.