Regulations of the Health Risk Assessments Review

The full text for the Regulations are promulgated and enforced on March 22th, 2023.

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 Manufacturers and/or importers (hereinafter referred to as “the applicants”) shall submit the designated tobacco products (hereinafter referred to as “the products”) to the central competent authority 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 that are not in commercialized packaging, not for sale, and in quantities not exceeding the required quantities for research or test are exempted from these regulations at the permission of the central competent authority.

The essential components of the products that shall be submitted alongside the products to the central competent authority for the health risk assessment review may be manufactured or imported on a case-by-case basis at the permission of the central competent authority.

The application in Paragraph 1 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, data, and materials about the products:

(1) Health risk research data that have been published, known to, or should reasonably be known to the applicants and

health risk comparisons with other tobacco products;

(2) Data on raw materials, additives, and other relevant ingredients;

(3) Data on emissions;

(4) Data on the testing methods for the substances in Subparagraph 2 and 3 of this Paragraph;

(5) Processing methods;

(6) Research data on addictive substances;

(7) Relevant data on the products' ability to induce people younger than 20 years of age and first-time smokers to use the products;

(8) Nicotine and tar yields of the minimum usage unit or in the emissions of the products;

(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 and the permission dates that the products are granted for sale;

(12) Specific measures, implementation methods and the commitments for the monitoring and control mechanisms for tobacco hazards prevention and control; and

(13) Other documents, data, and materials 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, data, and materials required in Paragraph 1 are incomplete, the central competent authority shall order the applicants to supplement the documents and/or data within a specified period of time. If the applicants fail to supplement the documents, data and/or materials within the specified period of time, the application shall be rejected.

International standards recognized by the central competent authority may temporarily 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 in any of the following circumstances:

(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 incident prohibited by this Act;

(3) Any emerging evidence that proves an obvious health impact; and

(4) Any incident 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 the 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.

De-identification is required for the information with personal data in Sub-paragraphs 1 to 3 of the preceding Paragraph.

If the applicants fail to comply with the provisions in Paragraph 1, the central competent authority shall order the applicants to make corrections within a specified period of time. If the applicants fail to make corrections within the specified period of time, the authorization for the products under the health risk assessment review shall be repealed.

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

Article 9 The central competent authority may authorize related professional institutions, agencies, legal persons or groups to execute the tasks in these Regulations.

Article 10 The Regulations shall be enforced on March 22, 2023.