

Regulations Governing the Declaration of Tobacco Product Information

1. Promulgated on December 4, 2008.
2. Amended on August 8, 2012.
3. Amended on March 22, 2023.

Article 1 These Regulations are enacted in accordance with Article 11 Paragraph 3 of the Tobacco Hazards Prevention Act (hereinafter referred to as "the Act").

Article 2 According to Paragraph 1 of Article 11 of the Act, information on domestically manufactured tobacco products shall be declared by the manufacturer, while information on tobacco products manufactured abroad shall be declared by the importer.

The aforesaid manufacturer and importer (hereinafter referred to as "the operators") shall provide data as listed in Schedule 1 to 4 ("the schedules") when declaring information on tobacco products ("the declared information"); however, tobacco products that do not generate emissions during use can be exempted from filling Schedule 4.

Article 3 When filling in the substance content in Schedule 2 to 4, the used testing methods shall be specified, and the test for declaration shall be conducted on the minimum unit of use or sale in accordance with the notes therein.

The aforesaid testing methods shall conform to applicable national standards, or to applicable international standards should no national standard is applicable.

Article 4 Should any field in the schedules is not applicable or deemed impossible to be filled in, the operator shall explain

the reasons and provide relevant evidence.

The declaration shall be filed in electronic forms, hard copies or other forms designated by the central competent authority by announcements.

Article 5 The operator shall complete the initial declaration for the brand, item, or identifier of any tobacco product initially manufactured or imported within thirty days after the payment of taxes under the Tobacco and Alcohol Tax Act and the Act.

In case of any change to the declared data following the initial declaration, the operator shall declare the change within thirty days after the date of the change.

From the year following completion of the aforesaid reporting, the operator shall conduct updated reporting on an annual basis, unless no manufacturing activity or importing transaction has been conducted in the proceeding two years.

The operator shall engage in the initial declaration for tobacco products manufactured or imported following being suspended for more than two years.

Article 6 The central competent authority may, if necessary, request the operator to provide supporting documents or samples related to the declared information, in quantities sufficient for the respective inspection/testing.

When the national standards apply to the aforesaid testing method and the declared information exceeds the allowable margin of error under the standard, the central competent authority shall request the operator to provide an explanation within 30 days of the date of submission, and

make the necessary corrections within a certain period.

Article 7 Should any declared information fails to meet the provisions of the Regulations, the central competent authority shall notify the operator to make corrections within 30 days from the date of declaration. Failure to make such corrections or to provide complete information shall be deemed as failing the declaration requirement.

Article 8 Operators may be exempted from declaration should the tobacco products are:

- (1) Intended for quality control or testing purposes;
- (2) Not packaged or intended for commercial sale, with a label clearly stating its purpose attached to the container; or
- (3) Intended for any specific purpose approved by the central financial authority and planned to be returned or destroyed within 30 days after the purpose is fulfilled.

Article 9 The central competent authority may delegate matters required by the Regulations to relevant professional authorities, institutions, legal persons or organizations.

Article 10 These Regulations shall enter into force on January 1, 2024.

Schedule 1

Item	Basic Information
1	Class of reporting: <input type="checkbox"/> Initial <input type="checkbox"/> Reporting change(s) <input type="checkbox"/> Updated reporting
2	Reporting operator (company name, telephone, address, and contact person):
3	Manufacturer (name of tobacco supplier):
4	Place of manufacturing (country/district):
5	<div> <div>Manufacturer's or importer's license number:</div> <div>Date of approval: ()</div> </div>
6	<div> <div>Date of reporting: ()</div> <div>Date of taxation: ()</div> </div>
7	Type of tobacco product: <input type="checkbox"/> Cigarette; <input type="checkbox"/> Cigar; <input type="checkbox"/> Cut tobacco; <input type="checkbox"/> Chewing tobacco; <input type="checkbox"/> Other (please specify): _____
8	Brand name:
9	Item name:
10	Item identifier:
11	Item identification documents: include as photos of the tobacco products, a copy of the certificate issued by the related inspecting/testing laboratory in compliance with ISO/IEC 17025 and a photocopy of the inspection/testing report within the past three years (containing at least test data on nicotine, tar and carbon monoxide, or the lowest detectable value or relevant reasons if related data is unavailable).
12	<p>Number of use units contained in each commonly sales unit (e.g. twenty cigarettes per pack, several cigars per pack, several pieces of chewing tobacco per pack, or certain grams of cut tobacco per pack):</p> <p>Common sales units: _____ Number of use units contained: <input type="checkbox"/> Pieces <input type="checkbox"/> Tablets <input type="checkbox"/> Grams <input type="checkbox"/> Other_____</p>
13	<p>Net weight of each use unit in grams (e.g. certain grams per piece or per sheet). Cut tobacco shall be reported in its minimum packing weight.</p> <p>_____ grams / <input type="checkbox"/> Piece <input type="checkbox"/> Tablet <input type="checkbox"/> Other (cut tobacco shall be reported as the weight of each unit as recommended)</p>
14	Necessary assembly: <input type="checkbox"/> Yes (color photos attached) <input type="checkbox"/> No
15	Other (please specify: _____)

Schedule 2

Item	Names of Materials and Substances of Tobacco (Ingredients) (For any unavailable field, please explain the reason)	Average weight (Reported in appropriate unit of measurement and noted)		Testing method	Related toxicity data source (Fill in at least one item based on the number of each item in the remarks)
		Unit of measurement mg, µg, ng, pg	Testing result		
1	Types of tobacco:				
	Tobacco			(NA)	
2	Rolling paper related substance				
	1) Raw materials			(NA)	
	2) Printing ink			(NA)	
	3) Bonding agent			(NA)	
3	Filter related material				
	1) Raw materials			(NA)	
	2) Printing ink			(NA)	
	3) Bonding agent			(NA)	
	4) Activated carbon			(NA)	
4	Tobacco-related components and heavy metals				
	1) Total nicotine (the total amount of nicotine extracted from tobacco)				
	2) N-nitroso-nornicotinine (NNN)				
	3) 4-methylnitrosamine-1-3-pyridine-1-butanone (NNK)				
	4) N-nitroso neonicotinoids (NAT)				
	5) N-nitrosoneonicotinine (NAB)				
	6) Arsenic (As)				
	7) Cadmium (Cd)				
	8) Chromium (Cr)				
	9) Lead (Pb)				
	10) Mercury (Hg)				
	11) Nickel (Ni)				
	12) Selenium (Se)				
5	Other				

Note:

- The data in each field of the form shall be reported based on the inspection (test) results of the user under Item 12 of Schedule 1.
- More than one component under any item in the form shall be reported in additional fields as necessary.
- The "Inspection/testing method" shall be reported using international common code (e.g. ISO 4387, ISO 10315, ISO 8454).
- "Related toxicity data source" shall be reported using the following codes:
 - Pyrolysis information
 - Identification of smoke composition, transport and pyrolysis

- ③ Emission test
- ④ In-vitro toxicity test
- ⑤ Skin or inhalation carcinogenicity test
- ⑥ Cardiovascular toxicity test
- ⑦ Inhalation test
- ⑧ Reproductive and developmental toxicity test
- ⑨ Addiction test
- ⑩ Safety Data Sheet (SDS)
- ⑪ Other technical data (with notes provided)

Schedule 3

Item	Class	Name of addendum	Average weight (Reported in appropriate unit of measurement and noted)		Testing method	Related toxicity data source (Fill in at least one item based on the number of each item in the remarks)
			Unit of measurement mg, µg, ng, pg	Testing result		
1	Addictiveness enhancer				(NA)	
2	Flavor				(NA)	
3	Preservative				(NA)	
4	Humectant				(NA)	
5	Coloring				(NA)	
6	Others				(NA)	

Note:

- (1) The data in each field of the form shall be reported based on the inspection (test) results of the user under Item 12 of Schedule 1.
- (2) More than one component under any item in the form shall be reported in additional fields as necessary.
- (3) "Related toxicity data source" shall be reported using the following codes:
 - ① Pyrolysis information
 - ② Identification of smoke composition, transport and pyrolysis
 - ③ Emission test
 - ④ In-vitro toxicity test
 - ⑤ Skin or inhalation carcinogenicity test
 - ⑥ Cardiovascular toxicity test
 - ⑦ Inhalation test
 - ⑧ Reproductive and developmental toxicity test
 - ⑨ Addiction test
 - ⑩ Safety Data Sheet (SDS)
 - ⑪ Other technical data (with notes provided)

Schedule 4

Item	Name of emission	Average weight (Reported in appropriate unit of measurement and noted)		Testing method	Related toxicity data source (Fill in at least one item based on the number of each item in the remarks)
		Unit of measurement mg, µg, ng, pg	Testing result		
1	Nicotine				
2	Tar				
3	Carbon monoxide				
4	Benzo[α]pyrene				
5	Benzene				
6	Formaldehyde				
7	Hydrogen cyanide				
8	Ammonia				
9	Acrylonitrile				
10	1, 3-butadiene				
11	Isoprene				
12	Toluene				
13	1-Aminonaphthalene				
14	2-Aminonaphthalene				
15	4-aminobinaphthalene				
16	Acetaldehyde				
17	Acrolein				
18	Crotonaldehyde				
19	4-methylnitrosamine-1-3-pyridine-1-butanone (NNK)				
20	N-nitroso-nornicotinine (NNN)				

Note:

- (1) The data in each field of the form shall be reported based on the inspection (test) results of the user under Item 12 of Schedule 1.
- (2) The "Inspection/testing method" shall be reported using international common code (e.g., ISO 4387, ISO 10315, ISO 8454).
- (3) "Related toxicity data source" shall be reported using the following codes:
 - ① Pyrolysis information
 - ② Identification of smoke composition, transport and pyrolysis
 - ③ Emission test
 - ④ In-vitro toxicity test
 - ⑤ Skin or inhalation carcinogenicity test
 - ⑥ Cardiovascular toxicity test
 - ⑦ Inhalation test
 - ⑧ Reproductive and developmental toxicity test
 - ⑨ Addiction test
 - ⑩ Safety Data Sheet (SDS)
 - ⑪ Other technical data (with notes provided)