Unofficial translation

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NO. 18 OF 2025
REGARDING
SUPERVISION OF TOBACCO PRODUCTS AND ELECTRONIC CIGARETTES

BY THE GRACE OF GOD, THE ALMIGHTY

THE HEAD OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering:

a. the provisions regarding the supervision of tobacco products in circulation, the inclusion of health warnings in advertisements and on the packaging of tobacco products, and the promotion of such products, as stipulated in Regulation of the Head of Indonesian Food and Drug Authority No. 41 of 2013 on the Supervision of Tobacco Products in Circulation, the Inclusion of Health Warnings in Advertisements and on the Packaging of Tobacco Products, and Promotion are no longer in line with legal requirements and developments in science and technology, and therefore need to be replaced;
b. that pursuant to Article 431(8), Article 432(5), and Article 439(1) of Government Regulation No. 28 of 2024 regarding Implementing Regulation of Law No. 17 of 2023 on Health, the Indonesian Food and Drug Authority is authorized to supervise tobacco products and electronic cigarettes;
c. that based on the considerations referred to in subparagraphs (a) and (b), it is necessary to enact a Regulation of the Indonesian Food and Drug Authority on the Supervision of Tobacco Products and Electronic Cigarettes;

Having regard to:

1. Government Regulation No. 28 of 2024 concerning Implementing Regulations for Law No. 17 of 2023 on Health (Official Gazette of the Republic of Indonesia of 2024 No. 135, Supplement to the Official Gazette of the Republic of Indonesia No. 6952);
2. Presidential Regulation No. 80 of 2017 on the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia of 2017 No. 180);

3. Indonesian Food and Drug Authority No. 21 of 2020 on the Organization and Operations of the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesiaof 2020 No. 1002) as amended by No. 13 of 2022 on Amendments to Regulation of the Indonesian Food and Drug Authority No. 21 of 2020 on the Organization and Operational Procedures of the Food and Drug Supervisory Agency (Official Gazette of the Republic of Indonesia of 2022 No. 629);
4. Regulation of the Indonesian Food and Drug Authority No. 23 of 2020 concerning the Organization and Work Procedures of Technical Implementation Units within the National Center for Drug and Food Testing and Development of the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia of 2020 No. 1004);
5. Regulation of the Indonesian Food and Drug Authority No. 19 of 2023 concerning the Organization and Operational Procedures of Technical Implementation Units at the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia of 2023 No. 611), as amended by Regulation of the Indonesian Food and Drug Authority No. 3 of 2025 concerning Amendments to Regulation of the Indonesian Food and Drug Authority No. 19 of 2023 concerning the Organization and Work Procedures of Technical Implementation Units at the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia of 2025 No. 39);

HEREBY DECIDES:

To enact: REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON THE SUPERVISION OF TOBACCO PRODUCTS AND ELECTRONIC CIGARETTES.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Regulation of Authority, the following terms shall have the following meanings:

1. Tobacco Product means any product that is wholly or partially made from tobacco leaves as its raw material, which is processed for use by burning, heating, vaporizing, smoking, inhaling, chewing, or by any other means of consumption.
2. Health Warning means text and images on the packaging that provide information and education regarding the dangers of smoking.
3. Head of the Authority means the Head of the Indonesian Food and Drug Authority.
4. Officer means an employee of the Indonesian Food and Drug Authority who is assigned to oversee addictive substances in the form of Tobacco Products and/or electronic cigarettes.

5. Business Entity means any individual or business entity, whether in the form of a legal entity or not, that is established and domiciled or conducts activities within the jurisdiction of the Republic of Indonesia, either individually or jointly, to carry out business activities involving the production, importation, and/or distribution of Tobacco Products and/or electronic cigarettes.

CHAPTER II
SUPERVISION

Article 2

(1) Officers shall carry out supervision of Tobacco Products and/or electronic cigarettes through inspections.
(2) The inspections referred to in paragraph (1) shall be conducted on business entities that produce, import, and/or distribute tobacco products and/or electronic cigarettes.
(3) Where verification is necessary, officers may conduct inspections of laboratories that test tobacco products and/or electronic cigarettes.
(4) The supervision referred to in paragraph (1) includes:
    a. supervision of nicotine and tar content;
    b. monitoring of ingredient lists and lists of prohibited additives; and
    c. monitoring the inclusion of health warnings and information on the label of each package.
(5) In carrying out the supervision referred to in paragraph (1), officers may take samples of tobacco products and/or electronic cigarettes to which excise stamps have been affixed.
(6) The supervision referred to in paragraph (1) does not apply to customs zones in accordance with the provisions of laws and regulations.

Article 3

(1) Tobacco products as referred to in Article 2 include:
    a. cigarettes;
    b. cigars;
    c. leaf cigarettes;
    d. sliced tobacco;
    e. solid and liquid tobacco; and
    f. other processed tobacco products.
(2) Electronic cigarettes as referred to in Article 2 are tobacco products in liquid, solid, or other forms derived from the processing of tobacco leaves, produced through extraction or other methods in accordance with technological advancements and consumer preferences, without regard to any substitute or auxiliary materials used in their manufacture, which are provided for end consumers in retail packaging

for retail sale, which are consumed by being heated using an electronic heating device and then inhaled.

(3) In addition to the electronic cigarettes referred to in paragraph (2), electronic cigarettes containing nicotine and/or other substances in liquid, solid, or other forms, and/or their derivatives—including synthetically produced substances of the same or similar type and nature—that are consumed by being heated using an electronic heating device and then inhaled are subject to the supervision referred to in Article 2.

CHAPTER III
IMPLEMENTATION

Part One
Supervision of Nicotine and Tar Content

Article 4

(1) The supervision of nicotine and tar content as referred to in Article 2, paragraph (4), letter a, shall be carried out in accordance with the following provisions:
   a. the nicotine and tar content for each variant of Tobacco Products; and
   b. the nicotine content for each variant of electronic cigarettes.

(2) Business entities that manufacture, import, and/or distribute tobacco products as referred to in paragraph (1)(a) must:
   a. hold a business license in accordance with applicable laws and regulations;
   b. comply with the maximum limits for nicotine and tar;
   c. test the nicotine and tar content for each variant of Tobacco Products produced and/or imported; and
   d. report the results of the nicotine and tar content testing referred to in subparagraph c to the Head of the Authority.

(3) Business entities that manufacture, import, and/or distribute electronic cigarettes as referred to in paragraph (1)(b) must:
   a. hold a business license in accordance with the provisions of laws and regulations;
   b. comply with the maximum nicotine content limit;
   c. conduct nicotine content testing for each variant of electronic cigarettes produced and/or imported; and
   d. report the results of the nicotine content testing referred to in subparagraph (c) to the Head of the Authority.

(4) The maximum limits for nicotine and tar content as referred to in paragraph (2)(b) and the maximum limit for nicotine content as referred to in paragraph (3)(b) shall be in accordance with the provisions of applicable laws and regulations.

(5) The tobacco product and/or e-cigarette variants referred to in paragraph (2)(c) and paragraph (3)(c) are tobacco products and/or electronic cigarettes containing the same ingredients.
(6) Testing of nicotine and tar content as referred to in paragraph (2)(c) and testing of nicotine content as referred to in paragraph (3)(c) shall be conducted in a laboratory accredited in accordance with the provisions of applicable laws and regulations.
(7) The testing referred to in paragraph (2)(c) does not apply to tobacco products for which no testing technology has yet been established in accordance with the provisions of laws and regulations.

Article 5

(1) Monitoring of nicotine and tar content as referred to in Article 4 paragraph (1) shall be carried out by the Head of the Authority by taking samples of products in circulation.
(2) The sampling of products in circulation as referred to in paragraph (1) shall be conducted at sale and/or distribution facilities.
(3) The sampling of products in circulation as referred to in paragraph (2) shall be carried out in accordance with the sampling guidelines established by the Head of the Authority.

Article 6

(1) The product samples referred to in Article 5 shall be tested in an accredited laboratory in accordance with the provisions of laws and regulations.
(2) Laboratory testing as referred to in paragraph (1) shall be conducted using analytical methods in accordance with the provisions of laws and regulations.

Part Two
Supervision of the List of Ingredients and the List of Prohibited Additives

Article 7

Business entities that manufacture, import, and/or distribute electronic cigarettes are required to report the list of ingredients and additives to the Head of the Authority.

Article 8

(1) Business entities that produce tobacco products and/or electronic cigarettes are prohibited from using additives unless it has been scientifically proven that such additives are not harmful to health.
(2) The prohibited additives referred to in paragraph (1) are in accordance with the provisions of applicable laws and regulations.

(3) In order to monitor the use of prohibited additives, business entities as referred to in paragraph (1) are required to conduct:
   a. testing prior to distribution; and
   b. verification during distribution.

(4) The testing and verification referred to in paragraph (3) must be conducted at different accredited laboratories.

(5) The results of the testing and verification referred to in paragraph (4) must be reported by the Business Operator to the Head of the Authority.

Article 9

(1) The reports referred to in Article 7 and Article 8 paragraph (6) shall be evaluated by the Head of the Authority.

(2) The evaluation referred to in paragraph (1) may take the form of testing product samples at an accredited laboratory in accordance with the provisions of laws and regulations.

(3) If, based on the results of the evaluation referred to in paragraph (1), it is found that a tobacco product and/or electronic cigarette contains prohibited additives, the Head of the Authority shall submit a recommendation for the product's recall to the minister in charge of trade affairs.

Part Three
Supervision of the Inclusion of Health Warnings and Information on the Label of Each Package

Article 10

(1) Business entities that manufacture, import, and/or distribute tobacco products and/or electronic cigarettes are required to include health warnings and information on the label of each package of tobacco products and/or electronic cigarettes.

(2) Supervision of the inclusion of health warnings and information on the label of each package of tobacco products and/or electronic cigarettes as referred to in paragraph (1) shall be carried out by the Head of the Authority by taking samples of products in circulation.

(3) The sampling of products in circulation as referred to in paragraph (2) shall be conducted at sale and/or distribution facilities.

(4) The product samples referred to in paragraph (3) shall be evaluated by the Head of the Authority.

(5) The evaluation referred to in paragraph (4) is conducted to ensure compliance with the provisions regarding the inclusion of health warnings and information on the labels of each package of tobacco products and/or electronic cigarettes.

Article 11

(1) The inclusion of Health Warnings as referred to in Article 10 paragraph (1) shall be subject to the following provisions:
   a. in the form of text accompanied by an image, included on the surface of the packaging;
   b. printed as an integral part of the packaging of the Tobacco Product or electronic cigarette packaging, and the packaging of nicotine refill liquid for electronic cigarettes; and
   c. shall be included at the top of the wider side of the front and back of the packaging.
(2) Each 1 (one) variant of a tobacco product and/or electronic cigarette must include health warning images and text consisting of 5 (five) different types, with each type accounting for 20% (twenty percent) of the total quantity of each variant of tobacco products and electronic cigarettes.
(3) The provision referred to in paragraph (2) does not apply to tobacco product manufacturers without Taxable Entrepreneur (PKP) status for VAT purposes whose total annual production does not exceed 24,000,000 (twenty-four million) sticks.
(4) Tobacco product manufacturers as referred to in paragraph (3) are required to include at least 2 (two) types of health warning images and text in accordance with the provisions of applicable laws and regulations.

Article 12

(1) The Health Warning images and text referred to in Article 11 shall be included on every smallest unit package and larger package of Tobacco Products and/or electronic cigarettes.
(2) Each package as referred to in paragraph (1) shall include 1 (one) type of graphic and text health warning.
(3) The provision referred to in paragraph (1) does not apply to klobot cigarettes, kelembak menyan cigarettes, and individually packaged cigars.
(4) The inclusion of the graphic and text referred to in paragraph (1) must meet the following requirements:
   a. they must be included on the upper portion of the wider side of the front and back packaging, each covering 50% (fifty percent) of the area, preceded by the word “Warning” in yellow letters on a black background; they must be printed clearly and conspicuously, either in part or in full;
   b. the images referred to in subparagraph (a) must be printed in color; and
   c. the font must be *Arial Bold* and proportional to the packaging, with yellow text on a black background.

(5) The Health Warning image and text referred to in paragraph (4) must not be obscured by anything, in accordance with the provisions of laws and regulations.

Article 13

(1) Business Entities that produce and/or import Tobacco Products as referred to in Article 10 paragraph (1) are required to include information on the label of each package in a clear and easily readable location, subject to the following provisions:
   a. the statement "contains nicotine and tar";
   b. the statement "sale or distribution to persons under 21 (twenty-one) years old and pregnant women is prohibited";
   c. the manufacturing code, date, month, and year, as well as the name and address of the business entity that manufactures the tobacco products; and
   d. the statements "there is no safe limit" and "contains more than 7,000 chemicals and more than 83 carcinogens" regarding tobacco products.

(2) Business Entities that manufacture and/or import tobacco products as referred to in paragraph (1) are prohibited from including:
   a. any misleading information or symbols, or promotional terms; and
   b. the words *"light," "ultra light," "mild," "extra mild," "low tar," "slim," "special," "full flavor," "premium,"* or other words that imply quality, superiority, safety, image, personality, or words with similar meanings.

(3) Business Entities that manufacture and/or import electronic cigarettes as referred to in Article 10, paragraph (1), are required to include information on the label of each package in a clearly visible and easily readable location, subject to the following provisions:
   a. the statement "contains nicotine";
   b. the statement "sale or distribution to persons under 21 (twenty-one) years old and pregnant women is prohibited";
   c. the manufacturing code, date, month, and year of production, as well as the name and address of the business entity that manufactures the electronic cigarettes; and
   d. it is prohibited to include any misleading information or symbols, or promotional language.

(4) The provisions referred to in paragraph (2)(b) and paragraph (3) do not apply to:
   a. Tobacco Products that have obtained a trademark registration certificate in accordance with the provisions of laws and regulations; and/or

b. Tobacco products carried by passengers, transportation crew, border crossers, shipments within specified quantities, or for the purposes of foreign state representations and their officials stationed in Indonesia based on the principle of reciprocity.

Article 14

The procedures for including the Health Warning as referred to in Articles 11 and 12, as well as the inclusion of information on the label of each package as referred to in Article 13, shall be carried out in accordance with the provisions of laws and regulations.

Part Four Technical
Procedures for Supervision

Article 15

The technical procedures for the supervision of tobacco products and/or electronic cigarettes as referred to in Article 2 shall be carried out in accordance with the technical guidelines established by the Head of the Authority.

CHAPTER IV
REPORTING

Article 16

(1) Business entities that manufacture, import, and/or distribute tobacco products and/or electronic cigarettes within the territory of Indonesia are required to submit reports to the Head of the Authority.
(2) The reporting referred to in paragraph (1) includes:
    a. the results of testing for nicotine and tar content in tobacco products;
    b. a list of ingredients and test results regarding nicotine content in electronic cigarettes;
    c. test results prior to distribution and verification during distribution regarding prohibited additives in tobacco products and/or electronic cigarettes; and
    d. the inclusion of health warnings and information on the label of every package of Tobacco Products and/or electronic cigarettes of a new brand and/or with a changed package design.
(3) Tobacco products and/or electronic cigarettes imported for product research and development purposes and not distributed are exempt from the reporting requirements referred to in paragraph (2).
(4) The reporting referred to in paragraph (2)(a), (b), (c), and (d) shall be accompanied by a statement certifying the accuracy of the information, on company letterhead bearing a sufficient revenue stamp and signed by the the head of the company.

(5) The reporting referred to in paragraph (2)(b) shall be accompanied by a certificate of analysis for each reported ingredient in the electronic cigarettes.

Article 17

(1) The reports referred to in Article 16, paragraph (2) subparagraphs (a), (b), (c), and (d) shall be submitted for each:
   a. new variant of Tobacco Products and/or electronic cigarettes that is produced or imported; and
   b. variant of Tobacco Products and/or electronic cigarettes that have undergone changes in ingredient composition or changes in the name of the manufacturer or importer.

(2) In the event that a variant of a tobacco product and/or electronic cigarette is no longer produced or imported, the business entity must submit a report to the Head of the Authority in the form of a statement of cessation of production or import.

Article 18

(1) The reporting referred to in Article 16, paragraph (1) shall be carried out through the Indonesian Food and Drug Authority's official website for reporting tobacco products and/or electronic cigarettes.

(2) In the event of a technical disruption on the official reporting website for tobacco products and/or electronic cigarettes of the Indonesian Food and Drug Authority as referred to in paragraph (1), reporting may be conducted non-electronically by submitting the report documents to the Indonesian Food and Drug Authority.

(3) Business entities must have access rights to the official Tobacco Products and/or Electronic Cigarettes reporting website of the Indonesian Food and Drug Authority prior to the reporting referred to in paragraph (1) is carried out.

(4) Access rights as referred to in paragraph (3) are obtained by completing the registration form on the official reporting website for tobacco products and/or electronic cigarettes of the Indonesian Food and Drug Authority.

(5) With regard to the reporting referred to in paragraph (1), the Head of the Authority shall verify the completeness and compliance of the report no later than 7 (seven) business days after the report is submitted.

Article 19

(1) The reporting of test results as referred to in Article 16 paragraph (2)(a), (b), and (c) must be accompanied by:
   a. a valid testing laboratory accreditation certificate; and
   b. a test result certificate signed by the person in charge of the accredited laboratory.

(2) The test result certificate referred to in paragraph (1)(b) must, at a minimum, contain:
   a. information on the Business Entity that manufactures, imports, and/or distributes Tobacco Products and/or electronic cigarettes, including:
      1. the business entity's identity;
      2. the excise business registration number; and
      3. the address, telephone number, and name of the head of the company.
   b. information on the accredited laboratory, including:
      1. the name of the laboratory; and
      2. address, phone number, and the person in charge of the laboratory.
   c. Sample information includes:
      1. the brand of the tobacco product and/or electronic cigarette;
      2. type of tobacco product;
      3. content, packaging, and manufacturing code of Tobacco products and/or e-cigarettes;
      4. a list of ingredients, for e-cigarettes; and
      5. test results for samples, including:
         a. test date;
         b. nicotine content;
         c. tar content, except for electronic cigarettes; and
         d. additives prohibited in tobacco products and/or e-cigarettes.

Article 20

(1) The report referred to in Article 16, paragraph (2)(d) must be accompanied by:
   a. a cover letter signed by the company's head; and
   b. samples of Tobacco Product packaging (packs and cartons) and electronic cigarette packaging (packs) consisting of 5 (five) different types of Health Warning images or 2 (two) different types of Health Warning images for tobacco product manufacturers without Taxable Entrepreneur (PKP) status for VAT purposes, 1 (one) copy of each.

(2) The cover letter referred to in paragraph (1)(a) must contain at least the following:
   a. information on the Business Entity that manufactures, imports, and/or distributes Tobacco Products and/or electronic cigarettes, including:
      1. the business entity's identity;
      2. the excise business registration number; and
      3. the address, telephone number, and name of the company's head.

b. information on tobacco products and/or electronic cigarettes, including the brand, type, contents, packaging, and form of packaging.

CHAPTER V
ADMINISTRATIVE SANCTIONS

Article 21

(1) Business Entities that violate the provisions referred to in Article 4 paragraph (2), Article 4 paragraph (3), Article 7, Article 8(1), Article 8(3), Article 8(5), Article 10(1), Article 11(2), Article 11(4), Article 13(1), Article 13(2), Article 13(3), and/or Article 16(1) shall be subject to administrative sanctions.

(2) The administrative sanctions referred to in paragraph (1) consist of:
   a. a warning;
   b. a stern warning; and/or
   c. product recall.

(3) The administrative sanctions referred to in paragraph (2) shall be imposed by the Head of the Authority.

(4) The Head of the Authority may submit recommendations based on the results of supervision to the relevant ministries or agencies in accordance with the provisions of laws and regulations.

(5) Recommendations based on the results of supervision as referred to in paragraph (4) shall take the form of:
   a. product recall; and/or
   b. enforcement action.

Article 22

The procedures for imposing administrative sanctions as referred to in Article 21 shall be carried out in accordance with the Regulation of the Indonesian Food and Drug Authority governing follow-up actions on the results of supervision of drugs, drug ingredients, narcotics, psychotropic substances, precursors, and addictive substances.

CHAPTER VI
FINAL PROVISIONS

Article 23

Upon the effective date of this Regulation of Authority, all provisions governing the advertising and promotion of tobacco products as set forth in Regulation of the Head of the Indonesian Food and Drug Authority No. 41 of 2013 concerning the Supervision of Tobacco Products in Circulation, the Inclusion of Health Warnings in Advertisements and on Tobacco Product Packaging, and Promotion (Official Gazette of the Republic of Indonesia Year 2013 Number 876), are hereby revoked and declared null and void.

Article 24

The provisions governing the supervision of tobacco products as stipulated in Regulation of the Head of the Indonesian Food and Drug Authority No. 41 of 2013 concerning Supervision of Tobacco Products in Circulation, the Inclusion of Health Warnings in Advertisements and on Tobacco Product Packaging, and Promotion (Official Gazette of the Republic of Indonesia Year 2013 Number 876), are hereby revoked and declared null and void as of July 26, 2026.

Article 25

The supervision of tobacco products and electronic cigarettes as regulated in this Regulation of Authority shall take effect on July 26, 2026.

Article 26

This Regulation of Authority shall take effect on the date of its promulgation.

To ensure public awareness, the promulgation of this Regulation of Authority is hereby ordered through its publication in the Official Gazette of the Republic of Indonesia.

Issued in Jakarta
on June 24, 2025

HEAD OF THE FOOD AND DRUG ADMINISTRATION,

Ditandatangani Secara Elektronik
BADAN POM

TARUNA IKRAR

Promulgated in Jakarta on
3rd of July 2025

DIRECTOR GENERAL FOR REGULATION,
MINISTRY OF LAW OF THE REPUBLIC OF INDONESIA,

Ditandatangani secara elektronik oleh :

DHAHANA PUTRA

OFFICIAL GAZETTE OF THE REPUBLIC OF INDONESIA YEAR 2025 NUMBER 470

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