



**FOOD AND DRUGS SUPERVISORY AGENCY  
OF THE REPUBLIC OF INDONESIA**

**REGULATION OF THE HEAD OF THE FOOD AND DRUGS SUPERVISORY AGENCY OF  
THE REPUBLIC OF INDONESIA  
NUMBER 41 OF 2013  
CONCERNING  
THE SUPERVISION OF TOBACCO PRODUCTS IN DISTRIBUTION, THE INCLUSION OF  
HEALTH WARNINGS IN ADVERTISEMENTS AND TOBACCO PRODUCT PACKAGINGS,  
AND PROMOTIONS**

**BY THE GRACE OF GOD ALMIGHTY  
THE HEAD OF THE FOOD AND DRUGS SUPERVISORY AGENCY  
OF THE REPUBLIC OF INDONESIA**

Considering :

that in order to implement the provisions of Article 60 paragraph (5) of Government Regulation Number 109 of 2012 concerning Health Safety Measures for Materials Containing Addictive Substances in the Form of Tobacco Products, it is necessary to determine a Regulation of the Head of the Food and Drugs Supervisory Agency of the Republic of Indonesia concerning the Supervision of Tobacco Products In Distribution, the Inclusion of Health Warnings in Advertisements, and Tobacco Product Packagings, and Promotions

In view of :

1. Law Number 36 of 2009 concerning Health (National Gazette of the Republic of Indonesia 2009 Number 114, Supplement to the National Gazette of the Republic of Indonesia Number 5063);
2. Government Regulation Number 109 of 2012 concerning Health Safety Measures for Materials Containing Addictive Substances in the Form of Tobacco Products (National Gazette of the Republic of Indonesia 2012 Number 278, Supplement to the National Gazette of the Republic of Indonesia Number 5380);
3. Presidential Decision Number 103 of 2001 concerning The Status, Tasks, Functions, Authority, Organizational Structures and Work Procedures of Non-Departmental Government Institutions as several times amended most recently by Presidential Regulation Number 3 of 2013;
4. Presidential Decision Number 110 of 2011 concerning Units of Organization and Tasks of Echelon I Non-Departmental Government Institutions as amended several times and most recently by Presidential Regulation Number 4 of 2013;



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5 Decision of the Minister for Industry and Trade Number 62/MPP/Kep/2/2004 of 2004 concerning Guidelines for Methods of Testing Nicotine and Tar Content Levels in Cigarettes;

6 Regulation of the Minister for Health Number 28 of 2013 concerning The Inclusion of Health Warnings and Health Information on Tobacco Product Packagings (National Gazette of the Republic of Indonesia 2013 Number 591);

7. Decision of the Head of the Food and Drugs Supervisory Agency Number 02001/SK/KBPOM concerning the Organizational Structure and Work Procedures of the Food and Drugs Supervisory Agency as amended by the Decision of the Head of the Food and Drugs Supervisory Agency Number HK.00.05.21.4231 of 2004;

8 Decision of the Head of the Food and Drugs Supervisory Agency Number 05018/SK/KBPOM concerning the Organization and Work Procedures of the Technical Implementation Unit in the context of the Food and Drugs Supervisory Agency as amended several times most recently by a Regulation of the Head of the Food and Drugs Supervisory Agency Number HK.00.05.21.3546 of 2009;

HAS DECIDED :

To determine :

A REGULATION OF THE HEAD OF THE FOOD AND DRUGS SUPERVISORY AGENCY OF THE REPUBLIC OF INDONESIA CONCERNING THE SUPERVISION OF TOBACCO PRODUCTS IN DISTRIBUTION, THE INCLUSION OF HEALTH WARNINGS IN ADVERTISEMENTS AND TOBACCO PRODUCT PACKAGINGS, AND PROMOTIONS

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Regulation what is meant by :

1 A Tobacco Product is a product which is wholly or partly made from tobacco leaf as a raw material which has been processed in order to be used by being burnt, smoked, and inhaled or chewed.



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2. Cigarette is a Tobacco Product which is intended to be burnt and smoked and/or of which the smoke is to be inhaled. Including clove cigarettes, white (i.e. non-clove) cigarettes, cigars or other forms (of smokeable) produced from the plant *Nicotiana tabacum*, *Nicotiana rustica*, and other species or their synthetic (forms) of which the smoke contains nicotine and tar, with or without additives.
3. Nicotine is the substance or material pyrrolidine contained in *Nicotiana tabacum*, *Nicotiana rustica*, and other species or their synthetic (forms) and which being addictive can result in dependency.
4. Tar is a smoke condensate which represents the total residue produced when cigarettes are burnt after the removal of nicotine and water (and which) is of a carcinogenic nature.
5. Commercial Advertisements for Tobacco Products, which hereinafter are referred to as Tobacco Product Advertisements, are commercial advertisements with the aim of introducing and/or popularizing goods to a targeted public in order to influence consumers to use the Tobacco Product offered.
6. Tobacco Product Promotion is the activity of introducing or disseminating information about a Tobacco Product in order to attract the consumer's interest in buying the Tobacco Product which will be and is being marketed.
7. Health Warning is images and text providing information about the dangers of smoking.
8. Health Information is information relating to health and which is included in Tobacco Product packaging.
9. Tobacco Product Packaging, which hereinafter is referred to as packaging, is the materials used to contain and/or package Tobacco Products whether in direct contact with the Tobacco Product or not.
10. A Label is any information concerning a Tobacco Product in the form of images or text or a combination of both, or in other forms, which is included with the Tobacco Product, inserted in it, placed on it, or represents a part of the Tobacco Product Packaging.
11. A Product Variant is a variation of a Tobacco Product brand.
12. An Agency Head is the Head of an Agency with tasks and responsibilities in the field of food and drug supervision.



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CHAPTER II

SCOPE

Article 2

The scope of this Head of Agency Regulation covers supervision which is conducted with regard to :

- a. Tobacco Products in Circulation
- b. Tobacco Product Advertising and Promotion

CHAPTER III

THE SUPERVISION OF TOBACCO PRODUCTS IN CIRCULATION

Part One

General

Article 3

The Supervision of Tobacco Products in Circulation is conducted in order to determine the truth of :

- a. nicotine and tar contents
- b. the inclusion of health warnings and health information on tobacco product packagings.

Part Two

Supervision of the Correctness of Nicotine and Tar Contents

Article 4

- (1) The Supervision of the Correctness of Nicotine and Tar Contents as intended in Article 3 letter a is to be conducted by undertaking sampling of Tobacco Products in circulation.
- (2) The sampling referred to in paragraph (1) may be performed at the point of sale and/or distribution
- (3) The sample referred to in paragraph (1) is to be undertaken in accordance with the sampling guidelines set by the Head of Agency.



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Article 5

- (1) Laboratory testing of samples as referred to in Article 4 is to be conducted to determine Nicotine and Tar content levels
- (2) Laboratory testing to test Nicotine and Tar levels is to be conducted in accordance with methods of analysis or test methods as specified according to the provisions of laws and regulations.

Part Three

Supervision of the Inclusion of Health Warnings and Health Information  
on Tobacco Product Packagings

Article 6

- (1) Supervision of the Inclusion of Health Warnings and Health Information on Tobacco Product Packagings as referred to in Article 3 letter b is to be performed by conducting sampling of Tobacco Products in circulation.
- (2) The sampling referred to in paragraph (1) can be conducted at the point of sale and/or distribution
- (3) With regard to the samples of Tobacco Products as referred to in paragraph (1) an assessment is to be conducted with regard to:
  - a. The obligation to include a health warning in the form of images and text;
  - b. The obligation to include :
    1. information about Nicotine and Tar content levels;
    2. a statement saying “Forbidden to be sold or provided to children under the age of 18 and to pregnant women”,
    3. the production code
    4. the date, month and year of production;
    5. the name and address of the producer.
  - c. Inclusion of the statement “there is no safe limit” and “contains more than 4,000 dangerous chemicals as well as more than 43 cancer-causing substances”, if included.



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d. Prohibitions

1. Inclusion of any misleading information or sign or words of a promotional character at all
2. Inclusion of the words “*light*”, “*ultra light*”, “*mild*”, “*extra mild*”, “*low tar*”, “*slim*”, “*special*”, “*full flavour*”, “*premium*” or other words indicating superior quality, a sense of safeness, image-making, personality or any words with the same meaning, except for Tobacco Products which have received a trade-mark certificate in accordance with the provisions of laws and regulations.

(4) Supervision of the inclusions referred to in paragraph (1), paragraph (2) and paragraph (2) is to be conducted in accordance with the provisions of laws and regulations.

Part Four

Reporting

Article 7

(1) In order to supervise tobacco products in circulation, producers and/or importers of tobacco products are obliged to report to the Head of Agency concerning :

- a. Nicotine and Tar content levels test results; and
- b. the inclusion of health warnings and health information on tobacco product packagings.

(2) The obligation to report as referred to in paragraph (1) letter b applies to tobacco products which are to be produced or imported with :

- a. new brands; and/or
- b. changes in packaging design.

(3) The reporting of those requirements as referred to in paragraph (1) letter b must be accompanied by a sample of the packaging.

(4) The procedure for reporting of those requirements as referred to in paragraph (1) letter a and letter b is listed in the Attachment which represents an inseparable part of this Regulation.



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Part Five

Inspections

Article 8

(1) In the event that a follow-up of results of supervision is undertaken of Tobacco Products in circulation, inspections may be conducted at :

- a. the cigarette industry; and/or
- b. cigarette testing laboratories

(2) The inspections referred to in paragraph (1) letter a can be accompanied by the collection of samples.

(3) The collection of samples as intended in paragraph (2) is to be limited to cigarettes to which excise tapes have already been applied.

CHAPTER IV

SUPERVISION OF TOBACCO PRODUCT ADVERTISING AND PROMOTION

Part One

Tobacco Product Advertising

Article 9

(1) The Supervision of Tobacco Products Advertising is to be undertaken in :

- a. the print media
- b. broadcast media
- c. information technology media; and/or
- d. outdoor media.

(2) Tobacco Products advertising as referred to in paragraph (1) must comply with the provisions of laws and regulations.

Part Two

Promotion of Tobacco Products

Article 10

Supervision of Tobacco Products Promotions is to be conducted by monitoring the ban on all tobacco product promotional activities; namely

- a. the provision of free discounts, Tobacco Product gifts, or other products which are associated with Tobacco Products;



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- b. the use of logos and/or brands of Tobacco Products on non-Tobacco Product goods or products; and
- c. the use of logos and/or brands of Tobacco Products in any institutional or individual activity.

CHAPTER V

ADMINISTRATIVE SANCTIONS

Article 11

(1) Apart from being subject to criminal sanctions in accordance with the provisions of laws and regulations infringements of the provisions of this Regulation may also be subject to administrative sanctions.

(2) The administrative sanctions as referred to in paragraph (1) may be in the form of :

- a. verbal warnings
- b. written warnings
- c. withdrawal of products, to be carried out by the producer or importer on the basis of a warrant of withdrawal from the Agency Head;
- d. recommendations for temporary suspension of activities; and/or
- e. recommendations for action to be taken by the relevant authorities in accordance with the provisions of laws and regulations.

CHAPTER VI

TRANSITIONAL PROVISIONS

Article 12

(1) Reports as referred to in Article 7 paragraph (1) letter a are to be submitted no later than 6 (six) months after the enactment of this Regulation and after that are to be reported whenever there is a change in the nicotine and tar content levels on the labels of tobacco products

(2) Reports as referred to in Article 7 paragraph (1) letter b are to be submitted no later than 23<sup>rd</sup> (the twenty-third) of June 2014, and after that are to be reported no later than 1 (one) month before the new brand or packaging design is released.





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CHAPTER VI

CONCLUDIDNG PROVISIONS

Article 13

This Regulation of the Head of Agency comes into force from the date of its enactment.

So that all persons may know about it, it is ordered that this Regulation be promulgated by placing it in the National Gazette of the Republic of Indonesia.

Determined in Jakarta  
on 28<sup>th</sup> June 2013  
HEAD OF THE FOOD AND DRUGS SUPERVISORY BODY  
OF THE REPUBLIC OF INDONESIA

signed

LUCKY S. SLAMET

Enacted in Jakarta  
on 28<sup>th</sup> June 2013  
MINISTER OF LAW AND HUMAN RIGHTS  
OF THE REPUBLIC OF INDONESIA

signed

AMIR SYAMSUDDIN

NATIONAL GAZETTE OF THE REPUBLIC OF INDONESIA 2013 NUMBER 876



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ATTACHMENT TO  
REGULATION OF THE FOOD AND DRUGS SUPERVISORY BODY  
OF THE REPUBLIC OF INDONESIA  
NUMBER 41 OF 2013  
CONCERNING  
THE SUPERVISION OF TOBACCO PRODUCTS IN DISTRIBUTION,  
THE INCLUSION OF HEALTH WARNINGS IN ADVERTISEMENTS AND  
TOBACCO PRODUCT PACKAGINGS, AND PROMOTIONS

REPORTING PROCEDURES

- I. REPORTING THE RESULTS OF NICOTINE AND TAR CONTENTS LEVELS TESTS
  1. Reports of the Results of Tests of Nicotine and Tar Contents Levels must be accompanied by:
    - a. A cover letter signed by the Chairperson of the Company.
    - b. A copy/photocopy of a currently valid Accreditation Certificate of the Cigarette Testing Laboratory.
    - c. A Test Results Certificate signed by the Responsible Person in the Cigarette Testing Laboratory, which contains the minimal following information:
      - 1) Producer/Importer information:
        - Name of Manufacturer / Importer
        - Business Identification Number for Excise (i.e. NPPBKC or *Nomor Pokok Pengusaha Barang Kena Cukai*)
        - Address
        - Telephone / Fax
        - Name of Owner / Director
      - 2) Testing Laboratory Information
        - Name of Laboratory
        - Address
        - Telephone / Fax
        - Responsible Person in Laboratory
      - 3) Sample Information
        - Cigarette Brand
        - Type
        - Contents / Packaging
        - Production code



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4) Results of Sample Testing

- Date of testing
- Nicotine Levels
- Tar Levels

2. Reports are to be sent to the Head of the Food and Drugs Supervisory Agency or, more specifically, to The Director of NAPZA (i.e. narcotics, psychotropics, and other addictive substances) Supervision at the following address:

Food and Drug Supervisory Agency  
Jl. Percetakan Negara No. 23  
Central Jakarta  
10560

II. REPORTING OF THE INCLUSION OF HEALTH WARNINGS AND HEALTH INFORMATION ON TOBACCO PRODUCT PACKAGINGS

1. Reports of the Inclusion of Health Warnings and Health Information on Tobacco Product Packagings are to be sent for each tobacco product variant.

2. Reports must be accompanied by:

a. A cover letter signed by the Chairman of the Company, which contains the following minimum information:

1) Manufacturer / Importer Information

- Name of Manufacturer / Importer
- Business Identification Number for Excise (i.e. NPPBKC or *Nomor Pokok Pengusaha Barang Kena Cukai*)
- Address
- Telephone / Fax
- Chairman / Director

2) Product Information

- Brand
- Type
- Contents / Packaging
- Form of Packaging : long rectangular packet / cylinder (filled according to the shape of the packaging)

b. An example of the tobacco product packaging (packs and cartons) consisting of 5 (five) kinds of different health warning graphics or 2 (two) kinds of different health warning graphics for those in the Tobacco Product Industry who are not Taxable Entrepreneurs, consisting of one of each kind and a copy.



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- c. Reports are to be sent to the Head of the Food and Drugs Supervisory Agency, or more specifically, to The Director of NAPZA (i.e. narcotics, psychotropics, and other addictive substances) Supervision at the following address:

Food and Drugs Supervisory Agency  
Jl. Percetakan Negara No. 23,  
Central Jakarta  
10560

**HEAD OF THE FOOD AND DRUG SUPERVISORY AGENCY  
OF THE REPUBLIC OF INDONESIA**

Signed

LUCKY S. SLAMET