

PRESIDENT REPUBLIC OF INDONESIA

REGULATION OF THE GOVERNMENT OF INDONESIA NUMBER 109 OF 2012 CONCERNING

CONTROL OF MATERIALS THAT CONTAIN ADDICTIVE SUBSTANCES IN TOBACCO PRODUCTS IN THE INTERESTS OF HEALTH

WITH THE BLESSINGS OF GOD ALMIGHTY

THE PRESIDENT OF THE REPUBLIC OF INDONESIA,

Considering

: that to implement the provisions of Article 116 of Law Number 36 of 2009 concerning Health, it is necessary to issue a Regulation of the Government concerning Control of Materials that Contain Addictive Substances in Tobacco Products in the Interests of Health;

Bearing in mind:

- 1. Article 5 clause (2) of the 1945 Constitution of the Republic of Indonesia;
- 2. Law Number 36 of 2009 concerning Health (State Gazette of the Republic of Indonesia of 2009 Number 144, Supplement to the State Gazette of the Republic of Indonesia Number 5063);

HAS DECIDED:

To issue: REGULATION OF THE GOVERNMENT CONCERNING CONTROL OF MATERIALS THAT CONTAIN ADDICTIVE SUBSTANCES IN TOBACCO PRODUCTS IN THE INTERESTS OF HEALTH.

CHAPTER I

GENERAL PROVISIONS

Article 1

In this Regulation of the Government:

- 1. Addictive Substance means a substance that causes addiction or dependence which endangers health, marked by behavioral and cognitive changes and physiological phenomena, a strong desire to consume the substance, difficulty in controlling its use, prioritizing the use of the substance over other activities, increased tolerance, and that can cause withdrawal symptoms.
- 2. Tobacco Product means a product that is wholly or partly made of tobacco leaf as its raw material that is processed for use by burning, sucking, and inhaling or chewing.
- 3. Smokeable means a Tobacco Product intended to be burned and sucked and/or its smoke inhaled, including kretek [clove] cigarettes, white cigarettes, cigars or other forms produced from the *nicotiana tabacum*, *nicotiana rustica*, and other species of plants or their synthesized equivalents which contain nicotine and tar, with or without additives.
- 4. Nicotine is a substance or pyrrolidine compound contained in *nicotiana tabacum*, *nicotiana rustica* and other species or their synthetic equivalents which is addictive and can lead to dependence.
- 5. Tar means the smoke condensate that is the total residue produced when smokeables are burned, net of nicotine and water, which is carcinogenic.
- 6. Commercial Advertising of Tobacco Products, hereinafter referred to as Tobacco Products Advertising, means commercial advertising with the aim of introducing and/or promoting goods to a target audience to influence consumers to use the tobacco products offered.
- 7. Promotion of Tobacco Products means activities to introduce or disseminate information about a tobacco product to generate consumer desire to buy tobacco products that will be and are being traded.
- 8. Tobacco Products Sponsorship, hereinafter called Sponsorship, means all forms of direct or indirect contributions in the form of funds or otherwise, by means of a variety of activities conducted by institutions or individuals, with the objective of exerting influence through promotion or use of tobacco products.
- 9. Label means any information about tobacco products in the form of graphics, text, a combination of both, or other form that is included with tobacco products, inserted into, placed on, or is part of the tobacco products packaging.
- 10. Packaging means the material used to contain and/or wrap tobacco products, whether in direct contact with the tobacco product or not.

- 11. Smoke Free Zone means a room or area that has been declared as a place in which smoking or the activities of production, sale, advertising and/or promotion of tobacco products are prohibited.
- 12. Any person means a natural person or a business entity, whether incorporated or unincorporated.
- 13. Central Government, hereinafter called the Government, means The President of the Republic of Indonesia who holds the power of the National Government of the Republic of Indonesia as referred to in the 1945 Constitution of the Republic of Indonesia.
- 14. Local government means the Governor, Regent, or Mayor and the Local Government Executive as elements of local government administration.
- 15. Minister means the minister who administers government affairs in the field of health.
- 16. Agency Head means the head of the agency with duties and responsibilities over the field of food and drug control.

Article 2

- (1) Administration of control of materials that contain addictive substances in tobacco products in the interests of health should not disrupt and endanger the health of individuals, families, communities, and the environment.
- (2) Administration of control as referred to in clause (1) shall aim to:
 - a. protect the health of individuals, families, communities, and the environment from the hazards of materials that contain carcinogens and addictive substances in tobacco products which can cause illness and death, and impair the quality of life;
 - b. protect the working-age population, children and adolescents from environmental pressures and the influence of advertising to initiate use and dependence on materials in tobacco products that are addictive;
 - c. increase public awareness and vigilance against the dangers of smoking and the benefits of living without smoking; and
 - d. protect public health from second-hand smoke.

Article 3

This Regulation of the Government regulates:

- a. Tobacco Products;
- b. responsibilities of the Government and Local Governments;
- c. administration;
- d. community participation; and
- e. guidance and oversight.

CHAPTER II

TOBACCO PRODUCTS

Article 4

Tobacco products regulated in this Regulation of the Government include smokeables [see definition at Article 1, Clause 3 above—Trans.] and other tobacco products used primarily by burning and sucking and/or inhaling the smoke, which contain addictive substances and other materials that are harmful to health.

Article 5

- (1) In addition to tobacco products referred to in Article 4, tobacco products which contain *nicotiana tabacum*, *nicotiana rustica*, and other species and/or their processed products, including manufactured synthetics of the same or similar type and nature as those produced by *nicotiana* species and their use by burning and sucking and/or inhaling the smoke is included in this Regulation of the Government.
- (2) Further provisions concerning tobacco products referred to in clause (1) shall be regulated by Ministerial Regulation.

CHAPTER III

RESPONSIBILITIES OF THE GOVERNMENT AND LOCAL GOVERNMENTS

Article 6

- (1) The Government and Local Governments, in accordance with their respective authorities, are responsible for regulating, administering, developing, and overseeing control of materials containing addictive substances in tobacco products in the interests of health.
- (2) The Government and Local Governments are responsible for providing access to information and education on control of materials containing addictive substances in tobacco products in the interests of health.

Article 7

- (1) The Government and Local Governments shall promote research and development activities within the framework of control of materials containing addictive substances in tobacco products in the interests of health.
- (2) The Government and Regional Governments shall promote diversification of tobacco products.

CHAPTER IV

ADMINISTRATION

Part One

General

Article 8

Administration of control of materials that contain addictive substances in tobacco products in the interests of health encompasses:

- a. production and import;
- b. distribution;
- c. special protection for children and pregnant women; and
- d. Smoke Free Zones.

Part Two

Production and Import

Article 9

Any person who produces and/or imports tobacco products must hold a license in accordance with statutory provisions.

Article 10

- (1) Any person who produces tobacco products in the form of smokeables is required to conduct testing of levels of nicotine and tar content per stick for each variety produced.
- (2) The provisions concerning testing referred to in clause (1) are not applicable to *klobot* [dried corn husk—*Trans.*] cigarettes, *klembak menyan* [aloeswood mixed with benzine gum incense—*Trans.*] cigarettes, cigars, and sliced tobacco.
- (3) The exemption referred to in clause (2) shall not apply where technological developments have made it possible to conduct testing of levels of nicotine and tar content on *klobot* cigarettes, *klembak menyan* cigarettes, cigars, and sliced tobacco.

Article 11

- (1) The testing referred to in clause (10) shall be conducted in a laboratory which has been accredited in accordance with statutory provisions.
- (2) The results of testing of the levels of nicotine and tar content as referred to in clause (1) shall be reported to the Agency Head.

Article 12

- (1) Any person who produces tobacco products is prohibited from using additives unless it has been scientifically proven that such additives are not harmful to health.
- (2) Additives which can be used in the production of tobacco products as referred to in clause (1) shall be stipulated by Ministerial Regulation.
- (3) Any person who produces tobacco products using additives that are dangerous to health as referred to in clause (1) shall be subject to administrative sanctions by the Minister in the form of recall of the product at the expense of the producer.

Article 13

- (1) Any person who produces and/or imports tobacco products in the form of machine-manufactured white cigarettes is prohibited from packaging fewer than 20 (twenty) sticks in each pack.
- (2) The provisions referred to in clause (1) are not applicable to tobacco products other than machine-manufactured white cigarettes.
- (3) Any person who produces and/or imports tobacco products in the form of machine-manufactured white cigarettes in packs of fewer than 20 (twenty) sticks in each pack as referred to in clause (1) shall be subject to administrative sanctions in accordance with statutory provisions.

Article 14

- (1) Any person who produces and/or imports tobacco products into the territory of Indonesia must include health warnings.
- (2) The health warnings referred to in clause (1) shall be in the form of pictorial images and text which must have one meaning.
- (3) The health warnings referred to in clause (2) shall be printed as an integral part of the tobacco product packaging.

Article 15

- (1) Each individual variety of tobacco product is required to be imprinted with pictorial images and textual health warnings consisting of 5 (five) different types, with a portion of each type being used on 20% (twenty percent) of the total of each variety of the tobacco product.
- (2) The provisions referred to in clause (1) are not applicable to tobacco products industries that are not Taxable Companies/Entrepreneurs [and] whose total production does not exceed 24 (twenty-four) million sticks per year.
- (3) The tobacco products industries referred to in clause (2) are required to imprint at least 2 (two) types of pictorial image and textual health warnings as stipulated by Ministerial Regulation.

Article 16

Further provisions on the pictorial image and textual health warnings referred to in Article 14 and Article 15 shall be regulated by Ministerial Regulation after coordination with the minister who administers governmental affairs in the field of finance.

Article 17

- (1) The pictorial images and textual health warnings referred to in Article 15 shall be imprinted on each of the smallest packs and larger packages of tobacco products.
- (2) Each package referred to in clause ... [drafting/typographical error has left out the clause number; presumably it is clause (1) above—*Trans*.] shall include (1) one type of pictorial image and textual health warning.
- (3) The provisions referred to in clause (1) are not applicable to *klobot* [dried corn husk—*Trans*.] cigarettes, *klembak menyan* [aloeswood mixed with benzine gum *Trans*.] cigarettes, and cigars packed singly.
- (4) Imprinting of pictorial images and text as referred to in clause (1) must meet the following requirements:
 - a. be imprinted on the outer layer of the packaging on the wide faces of both the front and back of the package, covering 40% (forty percent) of the broad side of the front and back of the package, preceded by the word "Warning" in white letters on a black background, which must be printed clearly and prominently, both partially and entirely;
 - b. pictorial images as stipulated in sub-clause a must be printed in color; and
 - c. Lettering must use *Arial Bold typeface*, size 10 *font* or be proportional to the packaging, with white text on a black background.
- (5) Pictorial images and text health warnings referred to in clause (4) may not be covered in any way in accordance with statutory provisions.

Article 18

Any person who produces and/or imports tobacco products without health warnings imprinted in the form of pictorial images and text as referred to in Article 14, Article 15 and Article 17 shall be subject to sanctions in accordance with statutory provisions.

Article 19

Any person who produces and/or imports tobacco products is required to imprint information on the levels of nicotine and tar content according to test results as referred to in Article 11 on the label of each package, placed so as to be clear and easy to read.

Article 20

Imprinting of information on levels of nicotine and tar content as referred to in Article 19

is required to be placed on the narrow side of each package of tobacco product, in a box with a 1 (one) millimeter border, with color contrast between the background color and that of the text, which shall be at least 3 (three) millimeters in size, in order to be clearly visible and easy to read.

Article 21

In addition to imprinting of information concerning the levels of nicotine and tar content as referred to in Article 20, the other narrow side of the package of tobacco product must also have imprinted:

- a. the statement "sale or supply of cigarettes to children under the age of 18 years and to pregnant women is prohibited"; and
- b. the production code, date, month, and year of production, as well as the name and address of the manufacturer.

Article 22

On the other side of the tobacco products packaging referred to in Article 20 can be imprinted the statement, "there is no safe limit" and "contains more than 4,000 harmful chemicals and more than 43 cancer-causing substances".

Article 23

Any person who produces and/or imports tobacco products without imprinting of information on the levels of nicotine and tar content referred to in Article 19, Article 20 and Article 21 shall be subject to administrative sanctions in accordance with statutory provisions.

Article 24

- (1) Each manufacturer is prohibited from including any information or symbols which are misleading or promotional wording.
- (2) In addition to the prohibitions referred to in clause (1), every manufacturer is prohibited from imprinting the words "Light", "Ultra Light", "Mild", "Extra Mild", "Low Tar", "Slim", "Special", "Full Flavor", "Premium" or other words that indicate quality, superiority, safety, image, individuality, or words with similar meanings.
- (3) The provisions of clause (2) are not applicable to tobacco products that have already obtained a brand/trademark certificate in accordance with statutory provisions.
- (4) Any person who produces and/or imports tobacco products which include any information or indications whatsoever which are misleading or wording that is promotional in nature as referred to in clause (1) shall be subject to imposition of sanctions in accordance with statutory provisions.

Part Three

Distribution

Article 25

Every person is prohibited from selling tobacco products:

- a. using vending machines;
- b. to children under the age of 18 (eighteen) years; and
- c. to pregnant women.

Article 26

- (1) The Government shall exercise control over tobacco products advertising.
- (2) Control over tobacco products advertising as referred to in clause (1) shall encompass the print media, broadcast media, information technology media, and/or outdoor media.

Article 27

Control of tobacco products advertising as referred to in Article 26, shall include, among others, the following:

- a. inclusion of health warnings in the form of pictorial images and text during at least 10% (ten percent) of the total duration of advertisements and/or 15% (fifteen percent) of the total area of the advertisement;
- b. include the symbol/text "18+" in the tobacco products advertising;
- c. not demonstrate, use, and/or display the object or shape of a smokeable or another term that can be associated with a brand of tobacco product;
- d. not feature a product name where the product is a smokeable;
- e. not make representations or suggestions that smoking provides health benefits;
- f. not use misleading words or phrases;
- g. not stimulate or encourage people to smoke;
- h. not depict children, adolescents, and/or pregnant women in pictorial and/or textual form;
- i. not be targeted at children, adolescents, and/or pregnant women;
- j. not use cartoon characters as models in advertisements; and
- k. not be contrary to community norms.

In addition to complying with the provisions referred to in Article 27, tobacco products advertising in print media must comply with the following requirements:

- a. not be placed on the front and/or back cover of the print media, or on the front page of a newspaper;
- b. not be placed adjacent to advertising of food and drinks;
- c. column width of advertisement cannot take up a full page; and
- d. not be published in print media for children, adolescents, and females.

Article 29

In addition to the control of tobacco products advertising referred to in Article 27, advertising in broadcast media can only be aired between the hours of 21:30 and 05:00 local time.

Article 30

In addition to the control of tobacco products advertising referred to in Article 27, advertising in information technology media shall comply with the provisions of the tobacco products trademark website which applies age verification to restrict access only to persons aged 18 (eighteen) years or older.

Article 31

In addition to the control of tobacco products advertising referred to in Article 27, advertising in outdoor media must comply with the following provisions:

- a. not be placed in Smoke Free Zones;
- b. not be placed on main or protocol roads;
- c. must be placed parallel to the shoulder of the road and may not block or transverse the roadway [requires clarification; does this mean adverts cannot be in the middle of lanes, on dividing strips, painted on the road surface, strung overhead, etc—

 Trans.]; and
- d. may not exceed 72 (seventy-two) square meters in area.

Article 32

In order to comply with availability of access to public health information and education, the Government and Local Government shall run public service announcements about the dangers of using tobacco products.

Further provisions on tobacco products advertising shall be regulated by regulation of the agency which administers governmental affairs in the field of broadcasting.

Article 34

Further provisions on tobacco products advertising in outdoor media shall be regulated by Local Governments.

Article 35

- (1) The Government shall exercise control over tobacco products promotion.
- (2) Provisions for control of tobacco products promotion as referred to in clause (1) shall be as follows:
 - a. not give away free of charge, at a discount, or prizes of tobacco products or other products associated with tobacco products;
 - b. not use a tobacco product logo and/or brand on products or items that are not tobacco products; and
 - c. not use a tobacco product logo and/or brand in institutional and/or individual activities.

Article 36

- (1) Any person who produces and/or imports tobacco products who sponsors an institutional and/or individual activity may do so only under the following conditions:
 - a. not use the trademarked names and logos of tobacco products including tobacco product brand images; and
 - b. not have the intent to promote tobacco products.
- (2) Sponsorship as referred to in clause (1) is prohibited for institutional and/or individual activities that are covered by the media.

Article 37

Any person who produces and/or imports tobacco products who becomes a sponsor in the form of corporate social responsibility may do so only under the following conditions:

- a. not use the trademarked names and logos of tobacco products including tobacco product brand images; and
- b. not have the intent to promote tobacco products.

Further provisions on procedures for the control of tobacco product sponsorship as referred to in Article 36 and Article 37 shall be regulated by Local Government.

Article 39

Everyone is prohibited from broadcasting and showing in the form of pictures or photographs, presenting, displaying or depicting a person smoking, displaying a cigarette, cigarette smoke, a pack of cigarettes or tobacco-related products and any form of information on tobacco products in the print media, broadcast media and information technology media related to commercial/advertising activities or that makes a person want to smoke.

Article 40

Any person who advertises and/or promotes tobacco products in a manner that does not comply with the provisions referred to in Article 27, Article 28, Article 29, Article 30, Article 31, Article 35, Article 36, Article 37, and Article 39, is subject to administrative sanctions by the Minister and/or the relevant minister consisting of:

- a. withdrawal and/or correction of the advertisement;
- b. written warning; and/or
- c. temporary prohibition on advertising of the subject tobacco product for repeat violations or serious violations.

Part Four

Special Protection for Children and Pregnant Women

Article 41

Implementation of protection of children and pregnant women against materials that contain addictive substances in tobacco products shall be carried out in an integrated and comprehensive manner through prevention, rehabilitation of physical and mental health, and social rehabilitation.

Article 42

Prevention activities referred to in Article 41 shall be conducted in order to give children and pregnant women an understanding of the adverse effects the use of tobacco products.

Article 43

(1) Activities related to rehabilitation of physical and mental health referred to in Article 41 shall aim to restore both the physical and the mental health of children and pregnant women affected by use of materials containing addictive substances in

- tobacco products.
- (2) Rehabilitation as referred to in clause (1) shall be effected through activities including, among others:
 - a. physical and mental examination;
 - b. treatment;
 - c. provision of psychosocial therapy;
 - d. provision of mental therapy; and/or
 - e. referral.
- (3) Rehabilitation as referred to in clause (2) shall be carried out by competent health personnel.

Article 44

- (1) Social rehabilitation activities referred to in Article 41 are intended to restore and develop the abilities of children who experience social dysfunction due to the use of materials containing addictive substances in tobacco products so that they can function normally in society.
- (2) Social rehabilitation activities referred to in paragraph (1) are carried out through social rehabilitation in the following ways, among others:
 - a. psychosocial motivation and diagnosis;
 - b. treatment and care;
 - c. vocational training and entrepreneurship development;
 - d. mental and spiritual counseling;
 - e. physical counseling;
 - f. social and psychosocial counseling;
 - g. accessibility of services;
 - h. social help and assistance;
 - i. resocialization counseling;
 - j. ongoing counseling; and/or
 - k. referral.
- (3) Further provisions on social rehabilitation as referred to in paragraph (2) shall be stipulated by regulation of the minister who administers governmental affairs in the social field.

Article 45

Any person who produces and/or imports tobacco products is prohibited from giving

tobacco products and/or items that resemble tobacco products free of charge to children, adolescents, and pregnant women.

Article 46

Directing a child/children under the age of 18 (eighteen) years to sell, buy or consume tobacco products is prohibited.

Article 47

- (1) In the conduct of any activity sponsored by tobacco products and/or intended to promote tobacco products, participation by minors under the age of 18 (eighteen) years is prohibited.
- (2) Any person who carries out activities sponsored by tobacco products as referred to in paragraph (1) in which minors under the age of 18 (eighteen) years participate shall be subject to sanctions imposed by the Local Government officials in accordance with their authority.

Article 48

- (1) In order to provide protection for children against the dangers of materials containing addictive substances in tobacco products, the Government and Local Governments shall provide a 24 (twenty-four) hour service post.
- (2) The service post referred to in clause (1) can be a hotline service or a call center.

Part Five

Smoke Free Zone

Article 49

Within the framework of administration of control of materials that contain addictive substances in tobacco products in the interests of health, the Government and Local Governments must designate Smoke Free Zones.

Article 50

- (1) Smoke free zones as referred to in Article 49 include:
 - a. health care facilities;
 - b. places of teaching and learning [i.e., schools and educational facilities—*Trans.*];
 - c. children's playgrounds;
 - d. places of worship;
 - e. public transportation;
 - f. workplaces; and

- g. such public places and other places as shall be designated.
- (2) The prohibition on sale, advertising and promotion of tobacco products is not applicable to places used for sale of tobacco products in the vicinity of a Smoke Free Zone.
- (3) The prohibition on production of tobacco products is not applicable to places used for production of tobacco products in the vicinity of a Smoke Free Zone.
- (4) The Management or caretakers of places referred to in clause (1) must establish Smoke Free Zones.

Article 51

- (1) Smoke Free Zone as referred to in Article 50 sub-clause f and sub-clause g may provide a special smoking place.
- (2) A special smoking place as referred to in clause (1) must be an open space in direct contact with outside air.

Article 52

Local Governments shall establish smoke free areas in their jurisdictions by Local Regulations.

CHAPTER V COMMUNITY PARTICIPATION

Article 53

- (1) The public can participate in the framework of control of materials containing addictive substances in tobacco products in the interests of health to achieve an optimal level of health.
- (2) Community participation as referred to in clause (1) can be undertaken by individuals, groups, legal entities or business entities, and institutions or organizations run by the community.

Article 54

Public participation as referred to in Article 53 can be carried out through:

- a. ideas and input regarding the establishment of policy and/or administration of programs for control of materials containing addictive substances in tobacco products in the interests of health;
- b. administration, providing assistance, and/or cooperation in research and development of control of materials containing addictive substances in tobacco products in the interests of health;
- c. acquisition and provision of facilities and infrastructure for conducting control of

materials containing addictive substances in tobacco products in the interests of health;

- d. participation in providing counseling and information and dissemination of information to the community in connection with administration of control of materials containing addictive substances in tobacco products in the interests of health; and
- e. overseeing activities and reporting violations discovered within the framework of administration of control of materials containing addictive substances in tobacco products in the interests of health.

Article 55

The role of the community in furtherance of the effort to secure materials containing addictive substances such as tobacco products for health conducted in accordance with the provisions of the legislation.

Article 56

In order to enhance community participation, the Government and Local Government shall cooperate with other relevant institutions to disseminate information and education on administration of control of materials containing addictive substances in tobacco products in the interests of health.

CHAPTER VI GUIDANCE AND OVERSIGHT

Part One

Guidance

Article 57

The Minister, relevant ministers, the Agency Head, and the Local Governments shall provide guidance on the administration of control of tobacco products as addictive substances in the interests of health by:

- a. establishing Smoke Free Areas;
- b. preventing people from beginning to smoke and counseling smokers to quit;
- c. providing information, education, and development of the capacity of the community to lead healthy lives;
- d. working with international agencies or institutions or community organizations to administer control of tobacco products as addictive substances in the interests of health in accordance with statutory provisions; and
- e. giving awards to persons or entities who have been instrumental in assisting the administration of control of tobacco products as addictive substances in the

interests of health.

Article 58

- (1) The Minister, relevant ministers, the Agency Head, and Local Governments shall undertake development efforts in order to diversify tobacco products whose use will be beneficial to health.
- (2) Diversification as referred to in paragraph (1) can be done by involving the community in efforts to protect the sustainability of the tobacco plant.

Part Two

Oversight

Article 59

- (1) The Minister, relevant ministers, the Agency Head and Local Governments shall oversee implementation of efforts to control materials containing addictive substances in tobacco products in the interests of health in accordance with their respective duties and functions.
- (2) In the framework of oversight as referred to in paragraph (1), the Minister, relevant ministers, the Agency Head, and Local Governments can take administrative action against violations of the provisions of this Regulation of the Government in accordance with statutory provisions.

Article 60

- (1) Oversight of tobacco products distributed and promoted, and imprinting of health warnings in advertising and packaging of tobacco products shall be carried out by the Agency Head.
- (2) Oversight of advertising, promotion and sponsorship as referred to in clause (1) shall be carried out by the Agency Head and coordinated with relevant agencies.
- (3) In conducting oversight of tobacco products in distribution, advertising and promotions as referred to in clause (1), the Agency Head can impose administrative sanctions consisting of:
 - a. oral warnings;
 - b. written warnings;
 - c. product recall;
 - d. recommendation for temporary suspension of activities; and/or
 - e. recommendation that the relevant agency take action in accordance with statutory provisions.
- (4) Recommendations referred to in clause (3) sub-clause d and sub-clause e must be carried out by the agency receiving the recommendation within a maximum period of 30 (thirty) days.

(5) Further provisions concerning the oversight of tobacco products in distribution, the imprinting of health warnings in advertising and tobacco product packaging, and promotions shall be regulated by the Agency Head.

CHAPTER VII TRANSITIONAL PROVISIONS

Article 61

Any person who produces and/or imports tobacco products must comply with the provisions of Article 14, Article 15 and Article 17 no later than 18 (eighteen) months from the promulgation of this Regulation of the Government.

Article 62

- (1) Any person who promotes and/or advertises tobacco products must comply with the provisions of Article 27, Article 28, Article 29, Article 30, Article 31, and Article 35 no later than 12 (twelve) months from the promulgation of this Regulation of the Government.
- (2) Any person who produces, imports and/or distributes tobacco products who sponsors an activity must comply with the provisions of Article 36 and Article 37 no later than 12 (twelve) months from the promulgation of this Regulation of the Government.

CHAPTER VIII CLOSING PROVISIONS

Article 63

Upon this Regulation of the Government coming into effect, all implementing regulations of Regulation of the Government No. 19 of 2003 concerning Control of Smoking in the Interests of Health (State Gazette of the Republic of Indonesia Year 2003 Number 36, Supplement to Statute Gazette No. 4276) shall remain valid insofar as they do not conflict with the provisions of this Regulation of the Government.

Article 64

Upon this Regulation of the Government coming into effect, Regulation of the Government No. 19 of 2003 concerning Control of Smoking in the Interests of Health (State Gazette of the Republic of Indonesia Year 2003 Number 36, Supplement to Statute Gazette No. 4276) is revoked and declared to be no longer in effect.

This Regulation of the Government shall take effect from the date of its promulgation.

In order that every person may know of it, the promulgation of this Regulation of the Government is ordered by placement in the State Gazette of the Republic of Indonesia.

Issued in Jakarta on December 24, 2012

PRESIDENT OF THE REPUBLIC OF INDONESIA

DR. H. SUSILO BAMBANG YUDHOYONO

Promulgated in Jakarta on 24 December 2012

MINISTER OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,
sgd.

AMIR SYAMSUDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA OF 2012 NUMBER 278

Issued as True Copy of the Original SECRETARIAT OF THE REPUBLIC OF INDONESIA Deputy Assistant for Legislation in the Field of Politics and People's Welfare,

Vishnu Setiawan



PRESIDEN REPUBLIK INDONESIA

ELUCIDATION

ON THE

REGULATION OF THE GOVERNMENT OF THE REPUBLIC OF INDONESIA NUMBER 109 OF 2012

CONCERNING

CONTROL OF MATERIALS THAT CONTAIN ADDICTIVE SUBSTANCES IN TOBACCO PRODUCTS IN THE INTERESTS OF HEALTH

I. GENERAL

Development of health as a national development effort is directed towards achievement of awareness, willingness and ability of every resident to live a healthy life, in order to achieve the optimal state of health.

In order to achieve the optimal degree of health for the community, a variety of health measures were implemented, one of which was a measure intended to control addictive substances, as stipulated in Articles 113, 114, 115 and 116 and Article 199 of Law Number 36 of 2009 on Health. In Article 113 clause (2) of Law No. 36 Year 2009 on Health, tobacco products were declared to be addictive substances.

In terms of human health, consumption of tobacco products, especially cigarettes, has become a polemic in itself, because the truth is that tobacco products that are burned contain more than 4,000 (four thousand) hazardous chemicals, including nicotine, which is addictive, and tar, which is carcinogenic.

Negative impacts of use of tobacco on health have long been known, and lung cancer is the number one cause of death in the world and [smoking—*Trans*.] can also cause heart attacks, impotence, hemophilia, emphysema, stroke and disorders of pregnancy and fetal development, all of which are preventable.

Smoking is detrimental to the health of both the smokers themselves and of the other people around them who do not smoke (passive smokers). Smokers have two to four times the risk of coronary heart disease and a higher risk of sudden death.

Incessant advertising, promotion and sponsorship has resulted in increased prevalence of smoking in children. Research has shown that advertising, promotion and sponsorship gives rise to the desire in children to start smoking, encourages the children of smokers to continue smoking and encourages children who have stopped smoking to take up smoking again.

Regulation of advertising as stipulated in Regulation of the Government No. 19 of 2003 on Control of Smoking in the Interests of Health is not optimal to prevent the increase in new smokers and given that tobacco products have been declared to be addictive substances pursuant to Article 113 clause (2) of the Health Act, the Government needs to control the advertising, promotion, and sponsorship of tobacco products.

There must be protection against exposure to the cigarette smoke of others (passive smoking), given that the risk of cancer for passive smokers is 30% (thirty percent) higher than for those who are not exposed to cigarette smoke. Passive smokers are also affected by other diseases suffered by smokers, among others, ischemic heart disease caused by cigarette smoke.

The community is entitled to information and warnings that are clear and correct about the effects of smoking. Although more than 90% (ninety percent) of the public have read the health warnings written on cigarette packs, almost half do not believe them and 26% (twenty six percent) are not motivated to quit smoking. Studies in a number of countries have proven that written warnings which are accompanied by pictures are more effective than written warnings alone. Therefore, health messages included on cigarette packaging must be in both pictorial and textual form to raise awareness of smokers and nonsmokers about the health hazards of smoking. To be effective, health warnings must be easily visible, relevant, and easy to remember and illustrate aspects that everyone should know about.

Control of tobacco products in the interests of health needs to be conducted through providing information about the levels of nicotine and tar contained in each cigarette, although, regardless of the content level, it is unsafe for consumption; the inclusion of health warnings on tobacco product packaging in pictorial and textual forms; regulation of production and sale of tobacco products; requirements for tobacco product advertising, promotion and sponsorship, and the principle of establishment of Smoke Free Zones.

Community participation in efforts to control tobacco products in the interests of health needs to be increased in order that the aim of this Regulation of the Government is optimally achieved.

Guidance and oversight by the Minister of Health, the relevant ministers and the Head of the Food and Drug Control Agency on the administration of efforts at controlling tobacco products in the interests of health shall be conducted in the various areas of responsibility in accordance with their respective duties and functions. Guidance and supervision shall be directed at guaranteeing the sustainability of the tobacco plant while still pursuing the development of the quality of tobacco plants in order to compete

with the quality of imported tobacco and to be able to meet the needs for tobacco by the domestic cigarette industry.

Control of tobacco products in the interests of health also needs to be carried out in an integrated manner across relevant sectors and with due regard to other statutory provisions.

II. ARTICLE BY ARTICLE

Article 1

Sufficiently clear.

Article 2

Sufficiently clear.

Article 3

Sufficiently clear.

Article 4

The term "other materials" means, among others, carbon monoxide and tar which contain 4,000 (four thousand) chemical compounds that are harmful to health.

Article 5

Clause (1)

Other tobacco products included in this provision refer to variants of other tobacco products which will be in existence at a later date in accordance with the developments in science and technology, the use of which will endanger health.

Clause (2)

Sufficiently clear.

Article 6

Clause (1)

Sufficiently clear.

Clause (2)

The form of information and education on control of materials containing addictive substances in tobacco products in the interests of health includes public service advertisements.

Article 7

Sufficiently clear.

Article 8

Sub-clause a

Regulation of production includes testing of levels of nicotine and tar content, use of additives, packaging and labeling, and health warnings.

Sub-clause b

Regulation of distribution includes sale, advertising, promotion and sponsorship.

Sub-clause c

Regulation of protection is targeted at children, adolescents and pregnant women in order to not make it easy to obtain tobacco products.

Subclause d

Regulation of Smoke Free Zones is designed to protect the health of individuals and the public from the dangers of second-hand smoke.

Article 9

Sufficiently clear.

Article 10

Clause (1)

The necessity to conduct testing of nicotine and tar content levels is intended to provide information to consumers about the hazards of smoking.

Clause (2)

Sufficiently clear.

Clause (3)

Sufficiently clear.

Article 11

Clause (1)

The definition of "a laboratory that has been accredited" is a laboratory that meets accreditation standards established by the competent institutions.

Clause (2)

Sufficiently clear.

Article 12

Clause (1)

The definition of "additives" is, among others, flavor enhancers, aroma enhancers, and coloring.

Cloves, *klembak* [Chinese rhubarb—*Trans.*], or incense are not considered additives but raw materials.

Clause (2)

Sufficiently clear.

Clause (3)

Sufficiently clear.

Article 13

Clause (1)

The purpose of the prohibition on making packs of cigarettes with fewer than 20 sticks is to make the price of cigarettes less affordable to consumers.

Clause (2)

The definition of "tobacco products other than machine-manufactured white cigarettes" includes, among others, hand-rolled kreteks [clove cigarettes— *Trans.*], machine-made kreteks, *klobot* [corn husk wrapped—*Trans.*] cigarettes, *klembak menyan* cigarettes [indigenous cigarettes made of tobacco leaves, Chinese rhubarb and incense—*Trans.*], cigars and sliced tobacco packaged in accordance with statutory provisions.

Clause (3)

Sufficiently clear.

Article 14

Clause (1)

The inclusion of health warnings in the form of pictorial images and text on tobacco product packaging is intended to educate and inform the public more effectively about the dangers of using tobacco products.

Clause (2)

The pictorial and text health warnings on any packaging of tobacco products must have the same meaning.

Clause (3)

The meaning of "printed as an integral part of the tobacco product packaging" is that health warnings shall not be a sticker affixed to the tobacco product packaging.

Article 15

Clause (1)

The meaning of "a portion of each type" is that for each type or brand produced, all five health warnings must be used.

For example:

1,000 packets of brand A will be produced in year X, so:

- 200 packets will include pictorial and textual health warning number 1;
- 200 packets will include pictorial and textual health warning number 2;
- 200 packets will include pictorial and textual health warning number 3;
- 200 packets will include pictorial and textual health warning number 4; and
- 200 packets will include pictorial and textual health warning number 5.

This is so that each type or brand does not just choose one of the five health warnings, but uses all five for each brand, one warning on each package.

Clause (2)

Sufficiently clear.

Clause (3)

Sufficiently clear.

Article 16

Coordination is conducted in terms of rotation of the types of pictorial health warnings.

Article 17

Clause (1)

In this regulation, the smallest package is defined as a package of smokeables that is in direct contact with the tobacco product, while larger packages, among others, include cartons.

The inclusion of pictorial and textual health warnings on packaging of both small and large packages is the most effective means of education for the public.

Clause (2)

Sufficiently clear.

Clause (3)

Sufficiently clear.

Clause (4)

Sufficiently clear.

Clause (5)

Sufficiently clear.

Article 18

Sufficiently clear.

Article 19

The obligation to include levels of nicotine and tar content aims to provide information to consumers about the health hazards of tar and nicotine. Besides causing dependence (addiction), nicotine can also cause constriction of blood vessels, including the coronary arteries that provide oxygen to the heart, and blood clots.

Due to the narrowing of blood vessels, the heart pumps or works harder, resulting in an increase in blood pressure [and] carbon dioxide binds with hemoglobin, replacing oxygen. The lack of oxygen flow to the heart muscle, coupled with the narrowing and blockage of the coronary artery, is what causes heart attacks. Whereas tar, which is carcinogenic, can cause cancer.

Article 20

Sufficiently clear.

Article 21

Sufficiently clear.

Article 22

Sufficiently clear.

Article 23

Sufficiently clear.

Article 24

Clause (1)

In this regulation, "misleading or wording that is promotional" means, among others, wording on the labels of tobacco products that is deceptive or tends to create a false impression about the health effects of tobacco products or conveys an impression that tobacco products provide some health benefit.

Clause (2)

The words "Light", "Ultra Light", "Mild", "Extra Mild", "Low Tar", "Slim", "Special", "Full Flavor" and "Premium" may be misleading because cigarettes are addictive and smokers will smoke more of them to satisfy their addiction to nicotine.

Unofficial Translation Clause (3) Sufficiently clear. Clause (4) Sufficiently clear. Article 25 Sub-clause a This prohibition is intended to put tobacco products beyond the reach of children. Sub-clause b This prohibition is intended to prevent sales to minors. Sub-clause c Sufficiently clear. Article 26 Sufficiently clear. Article 27 Sufficiently clear. Article 28 Sub-clause a The meaning of "front and/or back cover of print media" includes a page or cover stuck onto either the front or the back cover of print media. Sub-clause b Sufficiently clear. Sub-clause c Sufficiently clear.

Subclause d

Sufficiently clear.

Article 29

The term "broadcast media" means the electronic media, which includes television and radio.

Article 30

The term "information technology media" are all online media that use internet facilities.

Article 31

The term "outdoor media" is any object placed outdoors that is not used as a tool for supporting the activities of the production and distribution of tobacco products.

The outdoor media include, among others, billboards, displays, baliho [large movie posters made of hardwood—*Trans.*], posters, Megatron, stickers, banners strung between trees or poles, Bali flags, neon boxes, decorative lighting, signage, balloons, carts, houses, substations, motorbike depots, tents, buses, cars, motorcycles, bus stops, and tire covers.

Article 32

Sufficiently clear.

Article 33

Sufficiently clear.

Article 34

Sufficiently clear.

Article 35

Clause (1)

Sufficiently clear.

Clause (2)

Sub-clause a

The definition of "other products" is, among others, goods other than tobacco products that use the trademarks of or which may lead to the perception, whether directly or indirectly, of tobacco products.

Sub-clause b

Sufficiently clear.

Sub-clause c

Sufficiently clear.

Article 36

Sufficiently clear.

Article 37

Sub-clause a

The definition of "brand image" includes the slogan used by the tobacco product and colors associated as the hallmark of the subject tobacco product.

Sub-clause b

Sufficiently clear.

Article 38

Sufficiently clear.

Article 39

Provisions of the prohibition on broadcasting and depicting tobacco products include, among others, in movies, soap operas and other television shows other than news programs/news coverage.

Article 40

Sufficiently clear.

Article 41

Sufficiently clear.

```
Unofficial Translation
Article 42
     Sufficiently clear.
Article 43
     Sufficiently clear.
Article 44
     Sufficiently clear.
Article 45
     The definition of "products that resemble tobacco products" include food and/or
     beverages, including candy shaped like tobacco products.
Article 46
     Sufficiently clear.
Article 47
     Clause (1)
          The definition of "activity" includes, among others, music concerts.
     Clause (2)
          Sufficiently clear.
Article 48
     Sufficiently clear.
Article 49
     Sufficiently clear.
Article 50
     Clause (1)
          Sub-clause a
               Sufficiently clear.
```

Sub-clause b

Sufficiently clear.

Sub-clause c

Sufficiently clear.

Subclause d

Sufficiently clear.

Sub-clause e

The definition of "public transport" is public transportation equipment which can be land, water and air transport.

Sub-clause f

The definition of "workplace" is every enclosed or open space or area, whether mobile or fixed, in which people are employed or which is frequently entered by workers for purposes of a business and in which there is a source or sources of danger.

Sub-clause g

The definition of "public place" is all closed places accessible to the general public and/or places used together for community activities that are managed by government, private entities and the community.

The definition of "other places" is certain open places used jointly for public activities.

Clause (2)

Sufficiently clear.

Clause (3)

Sufficiently clear.

Clause (4)

Sufficiently clear.

Article 51

Clause (1)

Sufficiently clear.

Clause (2)

The definition of "open space" is a space with one side without a wall or roof so that cigarette smoke can escape directly into the open air.

Article 52

Sufficiently clear.

Article 53

Sufficiently clear.

Article 54

Sufficiently clear.

Article 55

Sufficiently clear.

Article 56

The definition of "relevant institutions" includes health care facilities, non-governmental organizations, professional organizations, educational institutions and youth associations.

Article 57

Sufficiently clear.

Article 58

Clause (1)

Diversification is intended for the use of tobacco products that are not harmful to health. Tobacco product diversification can be done by, among others, processing of tobacco leaves in order to obtain basic chemicals that can be used as pesticides, drugs, cosmetic products (skin tonics), for the pharmaceutical industry, and others.

Thus, the tobacco leaf can be used not just as the raw material for smoking but can also be used as a raw material for a diverse range of manufactured products.

Clause (2)

Sufficiently clear.

Article 59

Sufficiently clear.

Article 60

Clause (1)

Oversight by the Agency Head of the distribution of tobacco products in conjunction with the facts about nicotine and tar and labeling requirements as have been stipulated in this Regulation of the Government.

Oversight by the Agency Head of the distribution of advertising and promotion in conjunction with inclusion of health warnings in pictorial and textual form as well as the requirements stipulation in this Regulation.

Clause (2)

The definition of "relevant institutions" is institutions related to advertising, promotion, and sponsorship, among others, the Ministry of Communications and Information Technology, the Indonesian Broadcasting Commission, the Film Censorship Board, the Press Council, the Ministry of Education and Culture, the Ministry of Youth and Sports, the Ministry of Tourism and Creative Economy, the Ministry of Industry, the Ministry of Commerce, the Ministry of Finance, Provincial Governments and Provincial and District/Municipal Governments.

Clause (3)

Product recalls shall be conducted by the Directorate General of Customs and Excise, the Ministry of Finance and/or the Food and Drug Control Agency in accordance with their respective authorities pursuant to statutory provisions.

Clause (4)

Sufficiently clear.

Unofficial Translation
Clause (5)
Sufficiently clear.

Article 61
Sufficiently clear.

Article 62
Sufficiently clear.

Article 63
Sufficiently clear.

Article 64
Sufficiently clear.

Article 65
Sufficiently clear.

SUPPLEMENT TO STATE GAZETTE OF THE REPUBLIC OF INDONESIA NUMBER 5380