# **Legislation Template: Tobacco and Nicotine Products Control Act**

**International Legal Consortium, Campaign for Tobacco-Free Kids**

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**Introduction to the Template**

This template for the comprehensive regulation of tobacco and nicotine products and devices offers provisions that implement requirements of the WHO Framework Convention on Tobacco Control (WHO FCTC) and incorporate recommendations from the Guidelines for implementation of the treaty. This template modifies and updates previous versions developed by the International Legal Consortium of the Campaign for Tobacco-Free Kids.

This template is focused on WHO FCTC implementation of measures generally developed and issued by ministries responsible for public health. Therefore, this template does not contain draft text related to tobacco taxation or preventing the illicit trade in tobacco products as these measures are often developed by other ministries. In addition, the implementation of certain WHO FCTC Articles – for example, Article 12 on education, communication, training and public awareness and Article 14 on demand reduction measures concerning tobacco dependence and cessation – are not included in this template.

As new tobacco and nicotine products continue to emerge, legislative drafting will need to address both current and future product innovations. In this vein, the template: uses and defines terms broadly to capture all forms of tobacco and nicotine products for human consumption; applies FCTC-based legal measures according to current understanding of existing products; and authorizes the appropriate ministry to prescribe additional requirements as new evidence is solidified around the products.

***Treatment of Novel and Emerging Tobacco and Nicotine Products***

This template is drafted to enable the effective regulation of Electronic Nicotine Delivery Systems (ENDS) (or e-cigarettes), heated tobacco products, and other novel tobacco and nicotine products and devices in the same way as traditional tobacco products. *However, this is not intended to be a policy recommendation.* Some jurisdictions have elected to ban the manufacture, import, and sale of such products. Where such a ban is appropriate, some of the terms, definitions, and certain provisions in the template will likely need to be amended. *Please contact us at* ***LegalSupport@TobaccoFreeKids.org*** *for legislative drafting assistance on this issue.*

***Definitions***

The template uses broad definitions of tobacco and nicotine products in an effort to capture new product developments. The terms used for Electronic Nicotine Delivery Systems (ENDS) are “nicotine device” (for the devices that create the aerosol) and “nicotine product” (for the e-liquid or other nicotine containing substance). The term “nicotine product” also covers products such as oral nicotine pouches or nicotine lozenges that are not licensed nicotine replacement therapies. The term used for heated tobacco products is “tobacco device” (for the electronic heating device). The sticks or pods of heated tobacco are covered by the general definition of “tobacco product.”

**Use of the Template**

Any use of this template will need to be adapted to a country’s drafting customs and national context. We strongly encourage you to contact us at ***LegalSupport@TobaccoFreeKids.org***to discuss how to best utilize and adapt this template to your needs.

It is also important to note that bracketed, italicized text appears throughout the template where text needs to be filled in based on local context or policy decisions – e.g., identification of responsible entities, time frames. In addition, there are several notes throughout the template, as needed, to explain the importance of or rationale behind certain provisions.

**The Tobacco and Nicotine Products Control Act of \_\_\_\_\_\_**

**[or other name for the Act]**

An Act to provide for …

CHAPTER I – PRELIMINARY*[or other customary terminology generally used]*

***[Note: Preliminary matters might include a Short title, Commencement date, Objectives/purpose statement(s), and similar matters as appropriate and customary in the jurisdiction.]***

1. **Objects of the Act**

The objects of this Act are to -

***[Note: The Act’s objectives can play an important role in justifying the provisions of the Act. In the event of a legal challenge, courts often seek to determine whether and how the Act’s provisions are likely to accomplish the Act’s objectives. In drafting objectives, consideration might be given to articulating aims that include: those expressed in WHO FCTC Article 3 (Objectives) and in WHO FCTC Article 5.2(b)(Obligations); fulfilling the government’s WHO FCTC obligations and those relevant to other treaties to which the country is a party; preventing tobacco and nicotine product initiation and addiction, with special regard to young persons and other vulnerable population groups; encouraging quitting and preventing relapse; protecting the development and implementation of tobacco control policies from the commercial and other vested interests of the tobacco or nicotine product industry, etc. The objectives could also make connections with the government’s wider objectives for reducing non-communicable diseases and significantly contributing to its sustainable development goals and obligations.]***

CHAPTER II – INTERPRETATION

1. **Definitions**

In this Act, unless the context otherwise requires, –

“Additive” means a substance, other than tobacco or nicotine, added to a tobacco or nicotine product during processing, manufacturing, or packaging, and includes any substance that can be activated by the user.

[Note: The phrase “substance that can be activated by the user” is meant to cover such things as filter capsules that can add flavor when crushed by the user.]

“Advertising and promotion” means any form of commercial communication, recommendation, or action with the aim, effect, or likely effect of promoting, or promoting the use of, a tobacco or related product or a tobacco accessory, directly or indirectly.

“Characterizing flavor” means a clearly noticeable taste or smell, other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol, mint, chocolate, or vanilla, and includes any taste or smell subject to activation by the user.

“Contents”, with respect to –

1. a tobacco product, means tobacco, any additive and any other substance present in a finished tobacco product, including components such as paper, filter, ink, capsules, adhesives, and any processing aid, residual substance, and substance that migrates from the packaging, and
2. a nicotine product, means nicotine, any additive, and any other substance present in a finished nicotine product.

“Cross-border”, with respect to advertising and promotion and sponsorship, means that which originates within the territory of\_\_\_\_\_\_\_\_ [*name of country*] and enters or could be received in another territory, as well as that which originates outside the territory of \_\_\_\_\_\_\_\_\_ [*name of country*] and is received or accessible within the territory.

“Emission” means a substance that is released when a tobacco or related product is used as intended.

“Enclosed” means any space covered by a roof or having one or more walls or sides, regardless of the type of material used and regardless of whether the structure is permanent or temporary.

“Minister” means the Minister responsible for Health *[or other appropriate Ministry responsible for carrying out the Act]*and “Ministry” shall have a corresponding meaning.

“Nicotine device” means a device manufactured for consuming a nicotine product by producing an emission for inhalation and includes, whether or not sold separately, any item or part, other than a nicotine product, manufactured for use with the device.

“Nicotine product” means a substance or mixture containing nicotine manufactured for human consumption, other than a tobacco product.

[Note: The definitions of ‘nicotine device’ and ‘nicotine product’ are intended to be broad, with the aim of covering all products containing nicotine on the market presently, and all devices used to consume them, as well as new nicotine-containing products that will be developed and introduced in the future. Nicotine products on the market presently include the e-liquid used with an Electronic Nicotine Delivery System (ENDS) device and oral nicotine products such as nicotine pouches, lozenges, and sprays. The definition of ‘nicotine product’ would cover all of these products.

***The definition of ‘nicotine device’ would cover all the hardware of an ENDS, whether an open or closed system or a disposable.***]

“Open space” means any space that is not “enclosed”, as that term is defined in this Act.

“Packaging” means –

1. any pack or packet, carton, box, tin, bag, pouch, tube, bottle, or other container which contains a tobacco or related product,
2. any wrapper used to enclose a tobacco or related product or its other packaging, and
3. any other material or insertion attached to or included with a tobacco or related product or its other packaging.

“Person” includes a natural or juridical person.

[Note: This definition will not be necessary if “person” is defined broadly in an existing Act on interpretation of laws.]

“Person responsible for the premises” means the owner, manager, or other person in charge of a public place, workplace, or public transport vehicle.

“Prescribed” means prescribed in regulations**.**

[Note: This definition will not be necessary if it is already clear from an existing Act on interpretation of laws.]

“Public place” means a place accessible to the general public or a place for collective use, regardless of ownership or right to access.

“Public transport” means any vehicle used for carriage of members of the public, usually for reward or commercial gain, including taxis.

“Related product” means any tobacco device, nicotine product, or nicotine device.

***[Note: Many provisions in this template are applied to tobacco products, tobacco devices, nicotine products and nicotine devices. Using all these terms together is cumbersome and can make reading the text more difficult. Therefore, the phrase ‘tobacco and related product’ is used to cover all four terms.]***

*“*Sell*”* means to supply or offer to supply a product at wholesale or retail in \_\_\_\_\_\_\_\_\_ *[name of country]* for a fee or other consideration, and “seller” shall have a corresponding meaning.

“Smoke” means the emissions from a lit tobacco product or the emissions produced for inhalation from a tobacco or related product.

“Smoking” means being in possession or control of a tobacco or related product producing smoke, regardless of whether the smoke is being actively inhaled or exhaled.

“Sponsorship” means any form of contribution to any event, activity, organization, or individual with the aim, effect, or likely effect of promoting, or promoting the use of, a tobacco or related product or a tobacco accessory, whether directly or indirectly.

“Standardized packaging”, with respect to a tobacco or related product, refers to –

1. packaging required to have a uniform appearance, a plain color and texture, and standardized shape, size, means of opening, and packaging material;
2. packaging prohibited from having any branding, logos, or other promotional elements on, inside, or attached to the packaging or to the product, other than the brand name appearing in a standard size, color, and typeface, together with other permitted information;
3. requirements as to the standard appearance of an individual product or device, and the quantity of product contained in an individual package or container; and
4. any other requirements about any feature or element of the packaging or the appearance of the product or device.

“Tobacco accessory” means an item manufactured to be used in the consumption of a tobacco product, including: a pipe, water pipe, tobacco device and any item or part manufactured for use with the device, rolling papers, filters, and tubes sold separately from a tobacco product, and any other item designed to facilitate or enhance consumption of a tobacco product.

“Tobacco and related product industry” means manufacturers, importers, and wholesale distributors of any tobacco or related product.

“Tobacco control” means a range of supply, demand, and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products, nicotine use, and addiction, and exposure to emissions from the consumption of tobacco or nicotine products, and includes any policy, administrative, or legal measure relevant or related to tobacco control.

“Tobacco device” means a device manufactured for consuming a tobacco product by producing an emission for inhalation by means that do not involve full combustion of the tobacco and includes, whether or not sold separately, any item or part, other than a tobacco product, manufactured for use with the device. A device manufactured to allow the consumption of both a tobacco product and a nicotine product shall be considered a tobacco device.

“Tobacco product” means a product made entirely or partly from any part of a tobacco plant as raw material manufactured to be used for smoking, sucking, chewing, inhaling, or snuffing, or consuming by any other means.

“Workplace” means any place used by one or more persons during their employment, contract, voluntary, or other work, including any area used in or incidental to the course of work, as well as work vehicles.

1. **Exclusions**

A product that is regulated as a medicine or a medical device shall not be subject to regulation under this Act, with the exception of provisions under Chapter IV.

[Note: This exclusion is meant to cover licensed nicotine replacement therapies (NRT). In some countries it is possible for manufacturers to apply for a license that a specific ENDS is a medicinal product or device (similar to other NRT products). An ENDS licensed as a medicinal product or medicinal device will be regulated under the relevant medicines legislation and therefore should be excluded from regulation under tobacco control laws. However, the principle of smoke-free environments is that non-users should not be exposed to emissions generated by ENDS. Therefore, Chapter IV, on smoke-free environments, should apply to all ENDS including any that have been registered as medicinal products or licensed as NRT products.]

CHAPTER III – ADMINISTRATION

**Implementation and administration; authorities and duties; licensing**

[Note: Depending on country-specific factors, provisions for this Chapter might include:

1) The establishment of a tobacco control coordinating mechanism, as required by WHO FCTC Article 5.2(a). A tobacco control coordinating mechanism is an inter-agency, multi-sectoral institution established by the government to coordinate tobacco control within the country. Among its primary purposes are to provide political leadership and guidance to relevant sectors for tobacco control, enhance and facilitate the integration of tobacco control in government policies and program, and coordinate technical assistance for integrating tobacco control in critical government sectors at countries’ national and sub-national levels. Legislation may establish such elements of the coordinating mechanism as: membership; lines of authority; terms of membership and codes of conduct for members; roles and responsibilities of members; and the powers of the coordinating mechanism (in line with WHO FCTC Article 5.3). Guidance and resources for the establishment of a tobacco control coordinating mechanism can be found in WHO FCTC Convention Secretariat and UNDP’s Toolkit for Parties to implement Article 5.2(a) of the WHO FCTC, available at <https://www.who.int/fctc/implementation/cooperation/5-2-toolkit/en/> (last visited on November 1st, 2021).

2) Appointment and identification of the ministries or authorities with inspection powers and duties, what those powers and duties are, and how inspection authorities will coordinate with one another, unless these matters are comprehensively specified in an existing applicable law.

3) Licencing of tobacco or related product manufacturers, importers, wholesalers, retailers, and other businesses, unless licencing provisions already exist under an existing law that would be adequate to achieve tobacco and nicotine product control purposes. See the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products for a list of entities that should be subject to licencing.]

CHAPTER IV – SMOKE-FREE ENVIRONMENTS

1. **Protection against exposure to smoke**

Smoking is prohibited –

1. in any enclosed workplace;
2. in any enclosed public place;

[Notes: 1) Because apartment and condominium buildings and other types of multi-unit residences or facilities (e.g., residential care facilities) have aspects of private dwellings, workplaces, and common public spaces, and because smoke drifts out of individual dwelling units or areas, it may be advisable to specify the scope of smoking prohibitions with regard to both common areas and individual dwelling units or areas.

2) It may be further advisable to clarify the scope of smoking prohibitions with regard to a private residence that is also a workplace (e.g., in cases where child care to non-residents is provided, in cases where a non-resident provides domestic services in the dwelling, and in cases where a person operates a business out of his/her home and the dwelling is used as a workplace for employees of the business, etc.).]

1. on any means of public transport;
2. in any outdoor area that is –
   1. within \_\_\_ meters of a doorway, operable window, or air intake mechanism of any enclosed public place or workplace;

[Note: The required distance should be determined taking into consideration distance needed for effective protection, the boundaries of the premises, the proximity of the street to the enclosed structure(s) on the property, and other factors.]

* 1. an area for the service or consumption of food or drink, and within \_\_ meters of that area;
  2. a stadium, arena, or other performance space, and within \_\_\_ meters of that space;
  3. a waiting area or queue, including but not limited to public transport stops, and within \_\_\_ meters of that waiting area or queue*;* or

[Note: similar comment to (4)(a)]

* 1. designated as a no smoking area by the person responsible for the premises;

1. anywhere on the entire premises of a –
   1. child care facility or an educational or vocational facility at any level of instruction;
   2. health care facility;
   3. playground or amusement park; or
   4. public park; or
2. in any other prescribed outdoor area of a public place or workplace.
3. **Duties of persons responsible for the premises**

Persons responsible for the premises or the means of public transport in Article 4 shall ensure that –

1. signs are displayed notifying persons on the premises of the prohibitions on smoking, in a manner as may be prescribed;

***[Note: Ideally, the Minister would prescribe details for sign content, placement, etc. and provide a template for the signs. However, if there is concern that there may be delay in promulgating regulations, the law could specify the basic requirements for signs and authorize the Minister to supplement those requirements through regulations.]***

1. ashtrays are not present within the enclosed place or in any outdoor area where smoking is prohibited; and
2. reasonable steps are taken to stop a person from smoking where prohibited under Article 4, including any or all of the following:
   1. directing the person to stop smoking and if the person refuses, discontinuing service to that person;
   2. directing the person to leave the premises and, in the case of a public transport vehicle, to leave the vehicle when it is safe to do so;
   3. contacting law enforcement or other appropriate authority if the person refuses; and
   4. complaints by workers or members of the public are investigated and necessary actions are undertaken.

CHAPTER V— PROHIBITION ON ADVERTISING and PROMOTION AND SPONSORSHIP

1. **Comprehensive ban on all advertising and promotion and sponsorship**
2. All forms, methods, and means of domestic and cross-border advertising and promotion or sponsorship of tobacco or related products and tobacco accessories are prohibited and the following obligations apply –
3. No entity shall initiate, produce, publish, broadcast, or disseminate any advertising and promotion or sponsorship content.
4. Without prejudice to sub-article (a), an entity involved in analogue or digital media and communication, including any digital communication platform, shall –
   1. Monitor for and remove or disable any prohibited advertising and promotion or sponsorship content by means that may be prescribed by the Minister; and
   2. Establish an effective process and mechanism to allow organizations and individuals to notify the entity of content they suspect to be prohibited by means that may be prescribed by the Minister.
5. No person shall engage, participate in, or facilitate any sponsorship as a media or event organizer, venue owner, sportsperson, celebrity, artist, or other performer, as a provider or recipient of any sponsorship contribution, or intermediary that facilitates the sponsorship.
6. Without in any way limiting the broad application of this Article, the Schedule to the Act provides a non-exhaustive list of forms, methods, and means of advertising and promotion and sponsorship under the Act.
7. **Ban on display of products at a retail place of sale**
8. No person shall display or allow the display of a tobacco or related product, a tobacco accessory, or the packaging of a tobacco or related product or a tobacco accessory at a retail place of sale.
9. Visibility of a tobacco or related product or a tobacco accessory during a sales transaction shall not be considered to be a violation of sub-article (1).
10. A plain black-and-white-only price list for tobacco or related products and tobacco accessories, in a prescribed form, may be made available to retail customers upon request, provided that the list is not on general display and does not contain more than the brand name, package quantity or weight, price, and any other required or authorized information.
11. A sign, in a prescribed form and location, may be displayed at a retail place of sale that informs consumers that tobacco or related products and tobacco accessories are available for sale and that a price list is available on request.
12. **Incidental promotional effect**
13. Notwithstanding Article 6, the following, even if likely to have an incidental promotional effect, shall not be considered advertising and promotion or sponsorship –
14. a depiction of a tobacco or related product or its use where the depiction is justified by reasons of legitimate journalistic, artistic, or academic expression;
15. genuine political, social, editorial, or scientific commentary about a tobacco or related product or its use;
16. communications and product information necessary for business administration, trade between businesses in the tobacco or related products trade, or for required corporate reporting, but only to the extent access is limited to persons who need to receive it for business administration, trade, or corporate reporting; and
17. product manufacturers’ newsletters destined for and distributed only to the manufacturers’ employees, contractors, suppliers, and other related business partners, and only to the extent their distribution is limited to such persons.
18. Any communication or action pursuant to sub-article (1) shall not be false, misleading, or deceptive and shall be subject to any other requirements the Minister may prescribe.

[Note: Additional provisions might include requirements for: warnings attached to the communications in sub-article (1); no brand identification; reporting to the government on communications and actions undertaken pursuant to sub-article (1) that could help the government monitor and determine the legitimacy and necessity of the communication or action; certification by a corporate officer that no payment or other consideration was offered or made in exchange for any of the activities under sub-articles (1)(b)-(d); etc. See WHO FCTC Article 13 Guidelines recommendations on Legitimate expression, Depictions of tobacco in the entertainment media, and Communication within the tobacco trade.]

CHAPTER VI – PACKAGING AND LABELING

1. **Applicability**

This Chapter applies to packaging that is used for the retail sale of tobacco or related products and certain tobacco accessories.

1. **Warnings required on the packaging of tobacco or related products**
2. A person shall not manufacture, import, or sell a tobacco or related product unless its packaging displays the prescribed health warning and any other prescribed information.
3. Only prescribed warnings shall be displayed on or in the packaging of a tobacco or related product.
4. **Form, size, and placement of the health warnings on tobacco product packaging**
5. The packaging of a tobacco product shall display a health warning, as prescribed by the Minister, on each principal display area consisting of a picture and corresponding text in the \_\_\_\_\_\_\_\_ language *[specify the country’s principal language or languages]*.
6. The health warning prescribed under sub-article (1) shall occupy the proportion of each principal display area as determined by the Minister, which shall be no less than \_\_\_\_\_ %.

[Notes: 1) The WHO FCTC Article 11 Guidelines provide that the percentage of the principal display areas (PDAs) should be at least 50% or more, and that the larger the warnings, the more effective they are. Since the publication of the Guidelines, many countries have gone well beyond a 50% minimum size requirement and a size of 50% would be considered as lagging behind leading practice.

2) The Guidelines also recommend that the warnings be placed in the top portion of PDAs of individual packs. This can be specified in the law or left to the regulations and/or the electronic source document containing the images of the warnings to be displayed. Note that for cartons and other shapes where the width exceeds the length, placement of the warnings in the top portion of the PDAs will likely cause the images to be distorted, requiring warnings placement on the right or left side of the PDAs to avoid distortion of the warnings. Different placement requirements will also be needed for other packaging shapes.

3) Drafters should be familiar with the different types and shapes of packaging on the market in order to determine how warnings will best be displayed for the different kinds of packaging.]

1. The Minister may require the display of additional warnings or information messages in the form and manner prescribed on and inside the packaging of a tobacco product.
2. **Warnings required on tobacco device packaging**

The packaging of a tobacco device shall display a health warning as prescribed by the Minister and any additional warnings or information on and inside the packaging as prescribed.

1. **Warnings required on nicotine product and nicotine device packaging**

The packaging of a nicotine product and nicotine device shall display a health warning as prescribed by the Minister and any additional warnings or information on and inside the packaging as prescribed.

1. **Rotation of warnings** 
   1. The Minister shall prescribe a set of multiple warnings to be displayed on tobacco or related products for a period of time, the “rotation period”.
   2. The warnings from a prescribed set shall appear concurrently on an equal number of packages for each brand, brand family, and each package size and type.
   3. At the end of each rotation period, the warnings shall be replaced with the next set of prescribed warnings.

[Notes: 1) The WHO FCTC Article 11 Guidelines provide a period between 12 and 36 months should be an appropriate period for the display of a set of warnings/messages before they are required to be replaced with a new set. At the expiration of each rotation period, the warnings would be replaced with the next set of prescribed warnings.

2) Ideally, at least two sets of warnings would be made available at a time to make it less administratively burdensome, but if not, the next set would need to be made available sufficiently in advance of the end of a current rotation period.]

1. **Protection of the warnings on tobacco or related product packaging**

The warnings shall be permanently printed on the packaging of tobacco or related products and their full visibility and integrity must not be, and must not be susceptible to being, damaged, concealed, obstructed, or changed by any package design, feature, or mechanism, or covered by other markings.

1. **Contents and emissions information on packaging of tobacco products**
2. In addition to the required health warnings, the packaging of tobacco products shall display descriptive-only information on contents and emissions as prescribed by the Minister *[or other appropriate authority]*, including any requirements for rotation.
3. The packaging of a tobacco product shall not display any emission yields, including for tar, nicotine, and carbon monoxide.
4. Only the prescribed information on contents and emissions shall be displayed.
5. **Contents and emissions information on packaging of nicotine products and tobacco accessories**

The Minister may prescribe requirements for the display of contents and emissions information on packaging of nicotine product and tobacco accessories.

1. **Supply deadlines**

A tobacco or related product shall only be supplied in packaging that displays the prescribed warnings and contents and emissions information –

1. by a manufacturer or importer, no more than \_\_\_ days from the date of publication of the prescribed warnings and contents and emissions information; and
2. by a wholesaler or retailer, no more than \_\_\_ days from the date of publication of the prescribed warnings and contents and emissions information.

[Notes: 1) The WHO FCTC Article 11 Guidelines recommend making available a source document which contains high quality visual samples of how health warnings and other information are to appear on the packaging. Some countries provide electronic files with the images. The Guidelines consider that a period of up to 12 months from the date of enactment of the legal measures should be a sufficient period of time. Many countries provide a shorter time period, from 3 to 9 months.

2) The source document/e-files would need to be made available around the same time the regulations are enacted.]

1. **Duties not diminished by compliance**

The requirements of this Act for health warnings and contents and emissions information do not remove or diminish any duty of a manufacturer, importer, or wholesale distributor, including a duty to warn consumers ***[Note: if such a duty applies in the country pursuant to some other source of law]*** about hazards arising from the use of its product or device, or from exposure to their emissions.

1. **Prohibition on misleading packaging and products; regulation of promotional features of tobacco or related products**
2. The packaging of a tobacco or related product, and the product itself, shall not have any element or feature that –
   1. directly or indirectly creates or is likely to create the impression that a particular tobacco or related product is less harmful than any other tobacco or related product, unless otherwise permitted by the relevant competent authority;
   2. promotes the product by any means that are false, misleading, deceptive, or are likely to create an erroneous impression about its characteristics, health effects, hazards, or emissions; or
   3. creates or is likely to create the impression that the product has a characterizing flavor or contains any additive prohibited under Article 24.
3. The packaging of a tobacco product shall not use terms, including when used as part of a brand name or trademark, such as “low tar”, “light”, “ultra-light”, “mild”, “smooth”, “natural”, “organic”, “extra”, “ultra”, “menthol”, “slim”, or “smoke-free” or other terms in any language, that are likely to mislead consumers or suggest that the product has lifestyle or health benefits.

***[Note: Including legislative text limiting tobacco product brands to a single presentation is a specific measure Uruguay has taken to prevent deceptive branding of tobacco products. Under a ‘single brand presentation’ measure, only one brand variant is allowed for sale, which removes, for example, Marlboro Gold where Marlboro Red is for sale. Although this legislation template does not contain a single brand presentation requirement, it is a measure drafters may wish to consider including.]***

1. In this Article, an “element” or “feature”, whether or not part of the brand name, includes but is not limited to any term, descriptor, trademark, figurative, color, number, or other sign, and the dimension or shape of the packaging or product.
2. The Minister may prescribe, with respect to any tobacco or related product, requirements for preventing misleading packaging and product features.
3. **Standardized retail packaging of tobacco or related products**
4. Unless otherwise provided for in this Chapter, each inner and outer surface of the packaging of a tobacco or related product shall —
   1. be of a single prescribed color with a matt finish;
   2. not bear a trademark or other identifying mark or logo, other than in accordance with sub-article (3);
   3. not have any decorative ridges, embossing, or other embellishments;
   4. not contain an adhesive that is colored or non-transparent; and
   5. not contain any inserted items or affixed items other than as provided for by law.
5. Sub-article (1)shall not apply to the following —
   1. warnings or information as provided for under this Chapter;
   2. a bar-code or other similar identification mark in a prescribed form and location; or
   3. such other items or elements of the packaging as prescribed by the Minister or otherwise provided for by law.
6. The following may be printed on the packaging of a tobacco or related product, in a prescribed form and location —
   1. a brand name and product name; and
   2. the manufacturer’s name, address, and email address.
7. A plastic wrapper that covers a packet that contains a tobacco or related product shall —
   1. be transparent and without color;
   2. not have any decorative ridges, embossing, or other embellishments;
   3. not bear a trademark or other mark other than a tear-strip in a prescribed form; and
   4. not have any affixed item, other than as provided for by law.
8. A packet containing cigarettes shall —
   1. be cuboid in shape, without beveled or rounded edges;
   2. be a size that is within prescribed dimensions;
   3. be made of cardboard;
   4. have a prescribed form of opening; and
   5. contain 20 cigarettes.
9. Nothing in this Article or in regulations made under Article 21 shall operate to —
   1. prohibit the registration of a trademark under the [**relevant Trademarks or Intellectual Property Act**]; or
   2. be grounds for the revocation of the registration of a trademark under that Act.
10. **Authority of the Minister**

The Minister may make regulations –

1. prescribing all elements and features, the rotation, and any other details for health warnings and contents and emissions information required for tobacco or related products;
2. requiring the display of any additional information on the packaging of tobacco or related products, or as package inserts, to further the objectives of the Act; and
3. prescribing requirements for any element or feature of the packaging of a tobacco or related product, or a tobacco accessory, or the appearance of a tobacco or related product, or a tobacco accessory, including further requirements for standardized packaging.

CHAPTER VII – SALES OF TOBACCO OR RELATED PRODUCTS

1. **Regulation of sales practices**
2. No person shall sell a tobacco or related product, or a tobacco accessory, to a person under the age of 21 years or employ or use a person under that age to sell a tobacco or related product or tobacco accessory.

[Note: Nicotine can have negative life impacts on adolescents and young adults while the parts of the brain mostly responsible for decision making, impulse control, attention, and learning are still developing. Because brain development continues to about the age of 25 years, consideration should be given to setting a minimum sales age that is at least 21 years of age or up to age 25 years.]

1. Prior to any retail sale of a tobacco or related product or a tobacco accessory, the seller shall verify the age of the purchaser by checking a reliable form of identification, as may be prescribed by the Minister.
2. A seller of tobacco or related products or tobacco accessories shall place a clear and prominent sign inside the retail place of sale notifying consumers of the legal prohibition on sales to persons under age 21.
3. A seller shall ensure that a tobacco or related product is not directly accessible to a retail consumer prior to the sales transaction.
4. No person shall sell a tobacco or related product through a vending machine or other automated means.
5. No person shall sell, arrange for, or facilitate the retail sale of a tobacco or related product through sales by mail, the internet, or other remote means.

[Note: Internet sales are considered by the WHO FCTC Article 13 Guidelines to be a form of advertising and promotion, so the Appendix providing examples of advertising, promotion, and sponsorship includes internet sale. As a result, caution should be used to prevent duplicate or inconsistent penalties.]

1. No person shall sell a tobacco or related product within \_\_\_ meters of the property boundary of an educational facility or other facilities or locations as may be prescribed by the Minister.
2. The Minister *[or other appropriate authority]* may prescribe additional requirements related to the sale of tobacco or related products to prevent access by persons below the legal age for sale and to otherwise further the objectives of the Act.

CHAPTER VIII – REGULATION OF TOBACCO OR RELATED PRODUCTS; CONTENTS AND EMISSIONS AND Required DISCLOSURES

1. **Prohibition on certain additives; Regulation of contents**
2. No person shall manufacture, import, or sell a tobacco or nicotine product that –
   1. has a characterizing flavor;
   2. contains any additive with properties associated or likely to be associated with energy or vitality, a health benefit, or reduced health risk, such as but not limited to amino acids, caffeine, taurine and other stimulants, vitamins, and minerals, or is represented or suggested as containing any such additives or having such properties;
   3. contains any additive or mixture of additives with coloring properties for emissions; or
   4. has any feature allowing the addition or modification of a smell or taste of the product or its smoke intensity.
3. No person shall manufacture, import, or sell a tobacco product containing additives that enhance or increase the uptake of nicotine.
4. No person shall manufacture, import, or sell a product intended to be used by the consumer to add to or modify the smell or taste of a tobacco or nicotine product.

[Note: This provision is intended to cover products such as menthol cards that can be inserted into cigarette packs to flavor the tobacco after sale, or flavorings sold separately that can be added to e-liquids (nicotine products).]

1. No person shall manufacture, import, or sell a nicotine product that –
2. contains nicotine at a concentration greater than 20 mg/ml, or
3. is not in a child-proof and tamper-proof container in the case of a container for retail sale.

After \_\_\_ days from the date this Act takes effect, no person shall manufacture, import, or sell a tobacco or nicotine product unless it complies with the provisions of this article and any implementing regulations.

**[*Note: A deadline of up to 6 months from the date the Act is published in the Gazette should be sufficient.]***

1. **Authority of the Minister**

The Minister may prescribe requirements for the comprehensive regulation of tobacco or related products in furtherance of the objectives of the Act with respect to –

1. contents and emissions, including prescribing limits on or prohibition of any substance that may be contained in a tobacco or nicotine product or its emissions;
2. quality standards for any content contained in a nicotine product;
3. requirements, including quality standards, restrictions or prohibitions, for any feature or element of a tobacco or nicotine device, including but not limited to, materials used, heating capacity, size of components, and data exchange;
4. ignition propensity; and
5. testing and the methods for testing conformity with requirements under this Article.
6. **Disclosure of information related to tobacco or related products**
   1. Manufacturers and importers of tobacco or related products shall periodically, and upon request, submit information on product contents, emissions, and any other information prescribed in furtherance of the objectives of this Act.
   2. Submissions shall be in accordance with prescribed requirements for content, format and means, manner, frequency, and timing of submissions.

CHAPTER IX – PROTECTION OF TOBACCO CONTROL POLICIES FROM THE COMMERCIAL AND OTHER VESTED INTERESTS OF THE TOBACCO OR RELATED PRODUCT INDUSTRY

1. **Protection against the commercial and other vested interests of the tobacco or related product industry**
2. Government shall ensure that tobacco control policy setting and implementation are protected from the commercial and other vested interests of the tobacco or related product industry.
3. In this Chapter, “government” refers to institutions and instrumentalities of the State at the national and sub-national levels including parastatal institutions and instrumentalities, semi- or quasi-governmental institutions, bodies, boards, commissions, committees, work groups, or entities, and to persons working in government or engaged by government to work on its behalf.
4. “Responsibility for tobacco control” includes being involved in, contributing to, or being in a position to be involved in or contribute to tobacco control policy, including the formulation, implementation, administration, or enforcement of tobacco control policies, laws, regulations, programs, or initiatives at the national or sub-national level, and “responsible for tobacco control” shall have a corresponding meaning
5. **Adoption and implementation of policies**

The \_\_\_\_\_\_\_\_\_\_\_\_\_\_ [*responsible entity or entities*] shall develop policies and procedures, standards of conduct, and other instructions to further the effective implementation of this Chapter.

[Note: The responsible entity or entities under this provision will depend on how the government is structured and what body/bodies and mechanisms exist under current law for holding government officials and workers accountable.]

1. **Limitation on interactions between government and the tobacco or related product industry; transparency**
2. Government shall limit interactions with the tobacco or related product industry, and with any person working on behalf of the tobacco or related product industry, to only those strictly necessary, and only to the extent necessary, for effective regulation of tobacco or related products or the tobacco or related product industry.
3. Whenever any interaction under sub-article (1) occurs, regardless of which party initiates it, the interaction shall be transparent. Transparency requires government, at a minimum, to –
   1. conduct any meeting in public with advance public notice, unless doing so would jeopardize effective regulation or would not be legally possible, and
   2. document all interactions and make the documentation readily accessible to the public in a timely manner, subject to sub-article (3).

If disclosure of particular content in the documentation required by sub-article (2)(b) would likely jeopardize effective regulation or would not be legally possible, that content shall be subject to redaction and the basis for the redaction shall be noted as part of the disclosure.

1. **Prohibition on partnerships, endorsements, or involvement in tobacco control initiatives with the tobacco or related product industry**

Government shall not participate in, accept, support, or endorse any –

1. tobacco control or public health policy or legal or administrative measure drafted by or in collaboration with the tobacco or related product industry, or a person acting on behalf of that industry;
2. partnership or other voluntary arrangement with the tobacco or related product industry;
3. code of conduct or agreement that is not enforceable against the tobacco or related product industry in the place of legally enforceable tobacco control measures;
4. involvement in any manner by the tobacco or related product industry, or person acting on behalf of the industry, in any initiative, campaign, program, or activity directly or indirectly related to tobacco control or public health; or
5. financial, in-kind, or other contribution from the tobacco or related product industry or any person working on behalf of the industry.
6. **Prohibitions on preferential treatment and incentives**

Government shall not provide a business in the tobacco or related product industry, regardless of their ownership, management regime, or administration, with any tax exemption, financial or other incentive, privilege, or benefit to establish or run any of its operations.

[Note: If there are already privileges or incentives granted by a pre-existing law, that law would need to be amended or superseded by new legal provisions, as below. Any new laws generally granting subsidies, tax benefits, government procurement benefits, foreign direct investments, or the like, would likely need to exclude application of those benefits to the tobacco or related product industry.]

1. **Prevention and management of conflicts of interest**

Government shall implement measures to prevent and manage conflicts of interest related to tobacco or related products or the industry, including –

1. any direct interest, including any investment shares or other ownership interest in, or other financial dealings with, the tobacco or related product industry by any government body or person;
2. any contribution to government of any kind, gift, favor, or perquisite from the tobacco or related product industry or any person acting on behalf of the industry;
3. situations involving persons in, or under consideration for, government positions with responsibility for tobacco control who –
   1. are working concurrently in or on behalf of the tobacco or related product industry;
   2. worked in or on behalf of the tobacco or related product industry within a prescribed period of time before seeking a government position; or
   3. intend to work for or on behalf of the tobacco or related product industry within a prescribed period of time after leaving government service; and
4. any other conflict as may be prescribed or as may be specified in policies or procedures, codes of conduct, or other instructions for implementing this Chapter.

[Note: It might be advisable to indicate what range of actions in response to a conflict of interest government should take or prescribe, depending on the circumstances, e.g., disqualification from hiring or termination and/or limitations on the person’s functions, as the case may be; requiring divestment of previous financial interests and prohibiting acquisition of financial interests in the industry, requiring a waiting period before switching between government and the tobacco or related product industry, etc. See recommendation (4) of the WHO FCTC Guidelines for Implementation of Article 5.3.]

1. **Reports on tobacco or related product industry activities and practices**
2. Businesses in the tobacco or related product industry shall submit periodic reports containing prescribed information determined by the \_\_\_\_\_\_\_\_\_\_\_\_\_ to be appropriate for ensuring transparency of the activities, practices, and operations of the industry, for assessing the impact of those activities, practices, and operations on the government’s tobacco control program, for monitoring the industry, and for facilitating the effective implementation of this Chapter.

[Notes: 1) The government authority that will review the required information should be specified in the blank above, for example, an over-arching oversight body, focal point, or working group with the mandate to coordinate and oversee the implementation of WHO FCTC Article 5.3, or the MOH, who would then distribute the information to the relevant authorities if there is no over-arching body.

2) The WHO FCTC Article 5.3 Guidelines’ recommendations include requiring submission of information on tobacco production, manufacture, market share, marketing expenditures, revenues, and any other activity, including lobbying, philanthropy, political contributions, and all other activities not prohibited or not yet prohibited under WHO FCTC Article 13.]

1. The reports required pursuant to sub-article (1) shall be submitted in the manner and within the time periods prescribed, and upon request.
2. The Chief Operating Officer or Chair of the Board of the business submitting the report shall, under penalty of perjury, verify and attest to the truthfulness, accuracy, and completeness of the information reported.
3. The \_\_\_\_\_\_\_\_\_\_\_\_\_\_ shall maintain the reports for a prescribed period of no less than \_\_\_ years and shall make information from the reports readily accessible to the public in a timely manner; provided that reasonable action shall be taken to prevent disclosure of information, if any, that is protected by law, that is likely to be misleading, or that is likely to promote a tobacco or related product or a business in the tobacco or related product industry.

CHAPTER X – PENALTIES AND ENFORCEMENT

***Penalties***

***[Note: The nature of penalties should promote the values of social equity and justice by upholding human rights, protecting all vulnerable populations, and, as drafted, not patently threaten the safety and security of individuals in the application of criminal penalties.***

***The following principles, which are in accordance with the WHO FCTC Implementing Guidelines, should guide decisions about the level and nature of the penalties imposed:***

* ***Penalties should be graded and commensurate with the nature and seriousness of the offense.***
* ***Penalties should be sufficiently large to deter violations. This should mean imposing different levels of fines or criminal sanctions for the different provisions in the Act and regulations.***
* ***Larger penalties are required to deter business violators than to deter violations by individuals who have fewer resources. The resources for manufacturers and importers can be large and therefore fines and criminal sanctions must be sufficient to prevent violations by these actors.***
* ***Penalties should increase for repeated violations and should be consistent with a country’s treatment of other equally serious offenses. Repeat infringements by manufacturers should incur a highly significant penalty.***
* ***Sanctions should be applied to the conduct of corporate entities as well as individuals. Sanctions should be applied to the conduct of managers, directors, officers, and legal representatives that are responsible for corporate conduct.***
* ***In addition to monetary and/or criminal penalties, the legislation may also allow for administrative sanctions such as the suspension or revocation of business licenses (including retail, manufacturing or import licenses).***
* ***For violations of provisions on advertising, promotion and sponsorship, the legislation may provide for other means of remedying the infringement such as removal of the advertising or corrective statements.***
* ***The Act should set initial levels of fines but provide powers for these to be increased through regulations (to account for inflation).***

***If it would be possible to allocate the fines collected for violations, or a portion of them, a provision might be added for doing this. Some governments have established tobacco control funds for tobacco control implementation from various government revenue streams and contributions.]***

CHAPTER XI ‒ MISCELLANEOUS

1. **Corrective action**

In addition to any penalties imposed, the Court *[or administrative authority, if applicable]* may make an order for corrective action, including –

(a) recall, removal, and confiscation of advertising and promotion or sponsorship content;

(b) invalidation of any contract, agreement, or arrangement concerning advertising and promotion or sponsorship and forfeiture of any contribution prohibited under Chapter V or IX;

(c) recall, removal, and confiscation of any tobacco or related product that does not comply with prescribed requirements; and

(d) any other corrective action in respect of the objectives of this Act, as may be ordered in any judicial *[or administrative, if applicable]* proceeding*.*

1. **Presenting and acting upon complaints**

\_\_\_\_\_\_\_\_\_\_\_\_ shall establish institutional channels for the presentation of and action upon complaints regarding violation of the Act or implementing regulations.

1. **Introduction of new or substantially modified tobacco or related products to the market**

***[Note: This template uses broad definitions for tobacco and nicotine products and devices. These definitions are intended to cover any new or substantially modified products that come onto the market in the future. The consequence of this drafting approach means that any new products should be covered by all the substantive regulatory provisions. Some countries have taken an alternative approach and have sought to ‘freeze’ the market so that manufacturers and importers are banned from introducing new or substantially modified tobacco or nicotine products. In order to ‘freeze’ a market, tight definitions are required for the existing products that are already on the market (instead of the broad definitions used in this template). We recommend that any government that wants to take this alternative approach should contact the ILC for technical advice and assistance on drafting and policy development.]***

**Evaluation**

The Minister *[or other authority or authorities]* shall periodically evaluate the effectiveness of the Act, including the effectiveness of the inspection and enforcement program. Evaluation information shall be readily accessible to the public.

1. **Public awareness and civil society participation**

In implementing this Act, the Minister *[or other authority or authorities]* shall promote and strengthen public awareness of tobacco control issues and promote the full participation of civil society not affiliated with the tobacco or related product industry.

CHAPTER XII ‒ AUTHORITY TO MAKE REGULATIONS

1. **Regulations**

Without prejudice to the regulatory authority granted in other Chapters of the Act, the Minister *[or other relevant authority]* may make regulations –

1. necessary or appropriate to further the objectives of the Act;
2. for any consequential, incidental, supplementary, or transitional provisions relating to the provisions of the Act; and
3. for the effective administration of the Act.

[Note on concluding clauses: If not already provided for in an existing law on statutes construction or interpretation, it may be necessary or appropriate to specify additional matters, such as repeals of existing conflicting laws or provisions of laws, providing that if a particular provision is found by a court of competent jurisdiction to be unconstitutional, illegal, or otherwise invalid, all other provisions shall remain in full force and effect.]

SCHEDULE

**Indicative List of the Forms, Media, and Means of Tobacco and Nicotine Advertising and Promotion and Sponsorship Under the Act**

1. Communication related to a tobacco or related product through audio, visual or audiovisual means, such as print (for example, newspapers, sponsored news or infotainment content, magazines, pamphlets, leaflets, flyers, letters, billboards, posters, signs), television and radio (including terrestrial and satellite), streamed content, films, DVDs, videos and CDs, games (such as computer games, video games and online games), other digital communication platforms (such as the Internet, mobile phones, online social media platforms and mobile phone applications), and theatre and other live performance.
2. Communication related to a tobacco or related product through digital sharing media platforms, including paid product promotions, sponsored event promotions, competitions, boosting of promotional content by content hosts, influencer paid promotions, and tobacco or related product industry corporate (branded) promotion.
3. Direct person-to-person communications.
4. Brand-marking at entertainment venues and retail outlets and on vehicles and equipment or fixtures, such as by use of words, designs, images, sounds colors, brand names, trademarks, or logos, and any other indicia associated or likely to be associated with tobacco products, manufacturers, importers, or wholesalers.
5. Display of tobacco or related products using internet, telecommunications, or any evolving technology-based modes of sale.
6. Use of a tobacco or related product brand name, emblem, trademark, logo, trade insignia, or any other distinctive feature, in whole or in part, including color combinations, on or in connection with a non-tobacco or related product or service in such a way that the tobacco or related product and the non-tobacco or related product or service are likely to be associated.
7. Use of a brand name, emblem, trademark, logo, trade insignia, or any other distinctive feature, in whole or in part, including color combinations, of a non-tobacco or related product or service in connection with a tobacco or related product manufacturer, importer or wholesaler, in such a way that the tobacco or related product or company and the non-tobacco or related product or service are likely to be associated.
8. Product placement, such as the inclusion of or reference to a tobacco or related product, service or trademark in the context of communication in return for payment or other consideration;
9. Provision or offer of gifts or discounted products, such as key rings, T-shirts, baseball caps, cigarette lighters, CDs, other trinkets, or tobacco products, in connection with the purchase of a tobacco or related product.
10. Supply or offer of free samples of a tobacco or related product, including in conjunction with marketing surveys and taste testing.
11. Incentive promotions or loyalty schemes, such as redeemable coupons provided with the purchase of tobacco or related products.
12. Competitions associated with tobacco or related products or brand names, whether requiring the purchase of a tobacco or related product or not.
13. Direct targeting of individuals with promotional material, including informational material, such as direct mail, telemarketing, consumer surveys or research.
14. Promotion of discounted tobacco or related products.
15. Sale or supply of toys or sweets or other non-tobacco or non-nicotine products that resemble tobacco or related products.
16. Payments or other contributions of any kind to retailers aimed at encouraging or inducing them, or having the effect or likely effect of encouraging or inducing them, to sell tobacco or nicotine products, including retailer incentive programs, such as those that provide rewards to retailers for achieving certain sales volumes.
17. Promotional packaging and product design features.
18. Payment or other consideration in exchange for the exclusive sale or display of a particular tobacco or related product or particular manufacturer’s product in a retail outlet or at a venue or an event.
19. Sale, supply, placement, or display of tobacco or related products at educational establishments or at hospitality, sporting, entertainment, music, dance and social venues or events.
20. Provision of financial or other support to events, activities, individuals or groups, such as sporting or arts events, individual sportspeople or teams, individual artists or artistic groups, welfare and other public interest organizations, government institutions or organizations, politicians, political candidates, and political parties, whether or not in exchange for attribution, acknowledgement, or publicity, including corporate social responsibility activities of any kind.
21. Provision of financial or other support to venue operators, such as but not limited to pubs, clubs, and other recreational venues, in exchange for building, renovating, or decorating premises to promote a tobacco or nicotine product, or the use or provision of awnings, sunshades, or other items that promote a tobacco or nicotine product.
22. Any other tobacco or related product advertising and promotion or sponsorship in any form and by any method or means.