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Model Provisions for Alcohol, Cannabis, Tobacco, Nicotine, traditional drugs and related products control

Status and use:

This document constitutes the broadest and most detailed modular collection of model provisions for the regulation of alcohol, cannabis, tobacco, nicotine, vaping, traditional drugs, waterpipe products, nicotine products, and all related delivery devices, components, and services.

It complements and constitutes an alternative to, and a completion of the Regulatory Institute's Model Law on Alcohol, Cannabis and Tobacco Products which is more consistent, more concise and easier to use. On the other hand, these model provisions are way more complete and thus offer a broader choice to legislators. Both documents thus have pros and cons as starting points, whilst following largely the same order. To ensure that a bill is complete, it is preferable to use these model provisions as the primary reference. Moreover, the model provisions have a broader scope.

This document integrates the following sources, according to the AI tool used for its elaboration:

- Comparative enacted legislation from 40+ jurisdictions;
- WHO FCTC and its Protocols;
- The Regulatory Institute's Model Law on Alcohol, Cannabis and Tobacco Products;
- The first edition of the Regulatory Institute's Commonwealth and Latin American Legislators' Toolbox;
- The second edition of the Regulatory Institute's EU Legislators' Toolbox;
- The Regulatory Institute's Cross-sectoral Standard Provisions and its complementary List of Powers and Obligations and List of Sanctions and Collateral Measures.

Questions or suggestions? Please contact: manager@regulatoryinstitute.org

However, the Regulatory Institute's reference documents offer additional options that could further enhance the respective bill. This is in particular true for the following aspects: licensing or other conformity assessment procedures, obligations of economic actors, authority powers and (collateral) sanctions.

Moreover, the model provisions merit being complemented by additional technical requirements. The Regulatory Institute does not specialise in the field of alcohol, drug and tobacco prevention and therefore refrains from providing detailed requirements in these areas.

Conventions:

- Bracketed text requires particular jurisdiction-specific adaptation;
- "Alternative" provisions are mutually exclusive unless stated;
- Numerical limits are illustrative;
- "ACT Agency" = competent national authority;
- "Regulated Product" = any product, device, component, or service within scope.

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CHAPTER 1 — OBJECTIVES, SCOPE AND APPLICATION

Section 1 — Objectives, Interpretation and Implementation Principles

1.1 Objectives

The objectives of this Regulation are:

(a) to protect and improve public health, with particular regard to children, young persons, pregnant persons, persons affected by dependence, and communities experiencing disproportionate harm;

(b) to prevent or delay the initiation of the use of alcohol, cannabis, tobacco, nicotine and related-product use;

(c) to reduce the prevalence, frequency, harmful patterns, and intensity of use;

(d) to reduce dependence, poisoning, disease, injury, premature mortality, disability-adjusted life years lost, and social harm;

(e) to protect persons other than users from smoke, aerosol, vapour, second-hand and third-hand exposure, impaired conduct, violence, family disruption, environmental contamination and unsafe disposal;

(f) to control the commercial determinants of health by regulating the availability, accessibility, affordability, attractiveness, composition, manufacture, presentation, promotion, supply, distribution, and disposal of regulated products;

(g) to ensure that regulation is proportionate to the risks presented by a product, activity, person or place, applying a risk-based interpretation;

(h) to prevent illicit trade, diversion, adulteration, counterfeiting, regulatory circumvention, and tax evasion;

(i) to ensure effective registration, traceability, market surveillance, recall, enforcement, and cross-border cooperation;

(j) to promote cessation, treatment, harm reduction, and recovery without unjustified stigma or discrimination;

(k) to reduce environmental harm arising from cultivation, manufacture, packaging, batteries, plastics, emissions, chemical residues, and waste;

(l) to establish transparent, accountable, evidence-informed, and periodically reviewed systems of authorisation, monitoring, enforcement, and review;

(m) to protect public health policy from the commercial and other vested interests of regulated industries;

(n) to support education, research, and innovation in prevention, cessation, and harm reduction;

(o) to ensure a level playing field among economic operators and prevent regulatory arbitrage;

(p) to contribute to the achievement of the Sustainable Development Goals, particularly SDG 3 (Good Health and Well-being).

1.2 Interpretation

(1) This Regulation must be interpreted and administered in a manner that gives primary consideration to the protection of public health. In case of doubt, the interpretation protecting public health prevails; this applies also to conflicts between rules in this Subsection.

(2) Provisions must be interpreted consistently with international obligations.

(3) More specific provisions prevail over general provisions.

(4) Later provisions prevail over earlier ones unless otherwise stated or unless the latter are more specific.

1.3 Implementation principles

(1) This Regulation shall be implemented in accordance with the following principles:

(a) the polluter-pays principle;
(b) the user-pays principle for regulatory costs;
(c) the precautionary principle;
(d) the principle of proportionality;
(e) the principle of non-regression in public health protection;
(f) the principle of continuous improvement;
(g) the principle of transparency and public participation;
(h) the principle of evidence-based regulation; and
(i) the principle of intergenerational equity.

(2) In determining the controls applicable to a regulated product or regulated activity, the ACT Agency, the Minister, and a court may have regard to:

(a) the product's toxic, intoxicating, dependence-producing, or carcinogenic properties;
(b) its manner, frequency, duration, and route of administration;
(c) risks to children, young persons, pregnant persons, and vulnerable populations;
(d) risks to persons other than the user, including passive exposure;
(e) the likelihood of initiation, progression, dual use, substitution, or gateway effects;
(f) the scale and distribution of population harm;
(g) uncertainty in the available evidence;
(h) the practicability and likely effectiveness of available controls;
(i) the environmental impact across the product lifecycle; and

(j) the availability of less harmful alternatives.
(3) A lack of full scientific certainty does not prevent proportionate measures to avert or reduce a serious or irreversible risk to health (precautionary principle). However, the precautionary principle also requires that measures be:
(a) proportionate to the chosen level of protection;
(b) non-discriminatory in application;
(c) consistent with similar measures already taken;
(d) based on an examination of potential benefits and costs of action or inaction; and
(e) subject to review in light of new scientific data.

Section 2 — Scope and Application

2.1 Principal scope

(1) This Regulation applies to:

(a) alcoholic liquids and products containing alcohol intended or appropriate for human consumption;
(b) cannabis, cannabis-based goods, cannabinoids, and products containing them intended or appropriate for human consumption;
(c) tobacco, tobacco-based goods, and products containing tobacco intended or appropriate for human consumption;
(d) nicotine, nicotine-based goods, nicotine analogues, and products containing them intended or appropriate for non-medical human consumption;
(e) vapour inhalation products, whether or not they contain nicotine, tobacco, cannabis, or another psychoactive substance;
(f) heated products, whether containing tobacco, cannabis, herbal matter, or other substances;
(g) waterpipe, shisha, hookah, or narghile products, whether or not they contain tobacco or nicotine;
(h) oral tobacco products including snus, chewing tobacco, nasal tobacco, and dissolvable tobacco;
(i) tobacco-free nicotine products including nicotine pouches, strips, films, and powders;
(j) herbal smoking products and herbal products for inhalation;
(k) devices, components, accessories, software, and services used for the consumption, delivery, manufacture, or distribution of any product listed in (a) through (j);
(l) artificial cannabinoids, synthetic nicotine, and other designed psychoactive substances listed in Annex I;
(m) traditional psychoactive products listed in Annex II; and
(n) any additional product designated under Section 2.16.

(2) Cannabis-based goods include [notably]: liquid or consistent extracts of the cannabis plant, thus cannabis oil or hashish, and items which contain these extracts or the original

cannabis whilst being intended or appropriate for human consumption. Cannabis-based goods do [notably] not include textiles or textile based items derived from the cannabis plant or other items derived from cannabis which cannot be consumed by humans.

(3) Paragraph (2) applies by analogy to other psychoactive substances.

(4) This regulation applies finally to all items containing any of the above whilst still being intended or appropriate for human consumption.

2.2 Application regardless of intended use statements

A product remains within the scope of this Regulation notwithstanding any statement that it is not intended for human consumption, where its composition, presentation, marketing, customary use, or reasonably foreseeable use indicates otherwise.

2.3 Application to services and activities

This Regulation applies to:

(a) the manufacture, processing, assembly, repackaging, relabelling, and modification of regulated products;
(b) the import, export, transit, storage, transport, distribution, wholesale, and retail of regulated products;
(c) the advertising, promotion, sponsorship, endorsement, and commercial representation of regulated products;
(d) the operation of premises, venues, platforms, or services facilitating the consumption, sale, or distribution of regulated products;
(e) the provision of testing, certification, conformity assessment, or advisory services related to regulated products;
(f) the operation of online marketplaces, fulfilment services, delivery services, and payment services facilitating regulated product transactions;
(g) the cultivation of tobacco, cannabis, or other regulated plants;
(h) the disposal, recycling, and environmental management of regulated products and their waste; and
(i) the research, development, and clinical testing of regulated products.

2.4 Application to digital and distance activities

This Regulation applies to online activities and digital services relating to regulated products where:
(a) the activity originates from the jurisdiction;
(b) the service provider is established in the jurisdiction;
(c) the service is offered to users in the jurisdiction; or
(d) the service is directed at the jurisdiction, as evidenced by the use of the language, currency, top-level domain, delivery options, or targeting of the jurisdiction. Mere

accessibility of a digital service does not alone constitute directing activities at the jurisdiction.

2.5 Extraterritorial application

This Regulation applies to conduct engaged in outside the jurisdiction by any person where: (a) the conduct is directed at persons within the jurisdiction; (b) the conduct has a substantial effect within the jurisdiction; (c) the person is a national or resident of the jurisdiction; or (d) the person is a legal entity incorporated or carrying on business within the jurisdiction.

2.6 Products offered as a service

Products offered under a lease, rental, subscription, sharing, or "as a service" model are deemed placed on the market and subject to all regulatory obligations.

2.7 Direct installation and direct use

Where a product is supplied for direct installation or direct use without a separate "placing on the market" via selling, the supplier assumes the obligations of a manufacturer.

2.8 Surplus and non-installed products

Products manufactured but not placed on the market, or removed from installation, remain subject to this Regulation if subsequently made available.

2.9 Remanufactured and used products

(1) Remanufactured products are subject to the same requirements as new products unless the ACT Agency establishes specific derogations.

(2) Used products that have never been placed on the domestic market are treated as new products.

(3) Used products for which harmonised requirements exist are subject to those requirements upon re-entry into the market.

(4) The ACT Agency may establish voluntary conformity assessment pathways for used products.

2.10 3D-printing and digital manufacturing

(1) This Regulation applies to:

(a) 3D datasets placed on the market to permit the printing of regulated products;
(b) materials intended for 3D-printing of regulated products;
(c) 3D-printing services for regulated products; and
(d) devices used for 3D-printing of regulated products.

(2) A provider of 3D datasets for regulated products assumes the obligations of a manufacturer regarding design safety.
(3) A provider of 3D-printing materials must ensure compatibility with intended regulated products and provide safety information.

2.11 Systems and kits

(1) Several items jointly made available on the market and intended to be used together, comprising at least one regulated product ("systems"), are subject to this Regulation.

(2) Kits intended to be assembled by the user to become a regulated product are subject to this Regulation.
(3) The person assembling the system or kit for commercial purposes assumes manufacturer obligations.

2.12 Parts, components, and accessories

(1) Key parts of regulated products to which legal requirements apply are subject to this Regulation.
(2) Parts or materials intended for use in regulated products, where their manufacturer so requests, may be subject to voluntary conformity assessment. (3) Accessories specifically designed for regulated products are subject to applicable safety and information requirements.

2.13 Connected and smart products

Products incorporating software, connectivity, sensors, artificial intelligence, or remote-control functionality are subject to additional requirements concerning:
(a) cybersecurity;
(b) data protection;
(c) software updates;
(d) prevention of unauthorised modification;
(e) algorithmic transparency; and
(f) protection against dark patterns.

2.14 Exclusions

(1) This Regulation does not apply to:

(a) medicinal products authorised under applicable pharmaceutical legislation;
(b) medical devices authorised under applicable medical device legislation;
(c) food products regulated exclusively under food safety legislation, except where they contain alcohol, nicotine, or cannabinoids above prescribed thresholds;
(d) cosmetic products regulated under applicable cosmetics legislation;
(e) industrial products not intended for human consumption;

(f) classic pipes, waterpipes used solely as simple receptacles, glasses, and other basic containers without heating, atomizing, dosing, or electronic function;
(g) general-purpose batteries, cables, or electronic equipment not specifically designed for regulated products;
(h) products in transit through the jurisdiction under customs control, not intended for the domestic market; and
(i) alcoholic liquids with less than 1 percent alcohol per volume.

(2) A product does not qualify for exclusion under (a) or (b) merely because a therapeutic claim is made concerning it.

2.15 Anti-circumvention

(1) The application of this Regulation shall be determined by reference to a product's composition, design, presentation, marketing, customary or reasonably foreseeable use, commercial context, and effects, and not merely by its name, description, stated purpose, separation into components, or the manner in which its components are packaged or supplied.

(2) A product, component, service, or business model designed to formally escape this Regulation while producing or facilitating an effect that this Regulation is intended to regulate shall be treated as falling within its terms.

(3) The ACT Agency may determine that a specified product falls within the scope of this Regulation where it is substantially equivalent to a regulated product.

(4) Re-labelled, re-purposed, misdeclared, or "pseudo" products that are in substance regulated products shall be treated as such.

2.16 Designation of additional products

(1) The ACT Agency may, by regulation, designate a substance, preparation, article, component, service, or class of products as subject to this Regulation where it:

(a) produces intoxication, stimulation, sedation, or another psychoactive effect;
(b) delivers or facilitates delivery of alcohol, cannabis, tobacco, nicotine, or another psychoactive or dependence-producing substance;
(c) imitates the presentation, use, or sensory characteristics of a regulated product in a manner likely to normalise or encourage use;
(d) presents a material risk of poisoning, dependence, injury, exposure of other persons, or environmental harm;
(e) is materially interchangeable with a regulated product or component; or
(f) is used or likely to be used to circumvent this Regulation.

(2) Before making a designation, the ACT Agency must consider:

(a) the matters specified in Section 1.2;
(b) the need to avoid unjustified differences in treatment of products presenting comparable risks;
(c) whether designation is necessary to prevent avoidance; and
(d) the views of the Scientific ACT Committee. (3) A designation expires after [5] years unless reviewed and renewed.
(4) The ACT Agency may adopt emergency designations for [90] days where an imminent risk is identified.

2.17 Dynamic scope extension

(1) The ACT Agency shall maintain Annex I (list of designated substances) as a living document, updated to scientific progress and the emergence of ever new substances.
(2) The ACT Agency shall update Annex I at least annually or upon emergence of new evidence.
(3) Updates shall follow scientific assessment and consultation with the Scientific ACT Committee.

Section 3 — Definitions

a. ACT means alcohol, cannabis and tobacco and, where the context so requires, products, substances, preparations, articles or components added to the scope of this Regulation.
b. ACT Agency means the national administration or authority responsible for administering and enforcing this Regulation.
c. ACT Good means an item containing alcohol, cannabis or tobacco, or a derivative of any of them, intended or appropriate for human consumption, other than those explicitly exempted from the scope of this Regulation.
d. Active Substance means alcohol, caffeine, nicotine, taurine, THC or any other substance capable of modifying one's perception or self-perception;
e. Additive means a substance, other than the principal regulated substance, intentionally added to a product, component or emission.
f. Advertising means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a regulated product, brand, operator or consumption practice, whether direct or indirect, paid or unpaid.
g. Alcohol means ethyl alcohol intended or appropriate for human consumption.
h. Alcoholic Product means a liquid, solid, gel, powder or other preparation containing alcohol and intended or appropriate for human consumption.
i. Algorithmic System means any automated system that uses computational models, machine learning, or artificial intelligence to make or influence decisions regarding regulated products, including recommendation systems, pricing algorithms, targeting systems, and content moderation systems.

j. Beneficial Owner means any natural person who ultimately owns or controls an operator, directly or indirectly, through ownership of shares, voting rights, or other means.
k. Broker means a person who arranges, facilitates, or intermediates transactions in regulated products without taking ownership.
l. Cannabis-Based Good includes cannabis flowers, resin, hashish, oils, liquids, extracts, edible products and other items containing cannabis or cannabinoids and intended or appropriate for human consumption.
m. Cannabis Social Club means a non-profit membership association cultivating and distributing cannabis exclusively among its adult members for personal use.
n. Characterizing Flavour means a clearly noticeable smell, taste, or other sensory effect other than the basic character of the product, produced by an ingredient, capsule, component, package, accessory, or technical feature, perceptible before or during consumption.
o. Connected Device means a regulated device incorporating software, wireless connectivity, sensors, or remote-control functionality.
p. Consumer Unit means a quantity of a regulated product intended for retail sale to one consumer, within prescribed limits. Illustrative consumer-unit limits are: (1) 0.1 to 1 litre for alcoholic beverages; (2) 1 to 3 grams for cannabis; (3) 20 to 25 cigarettes, cigars, cigarillos or grams of tobacco; (4) 2 to 10 millilitres of refill liquid; (5) 1 to 2 millilitres in a pre-filled cartridge or tank; (6) 15 to 25 nicotine pouches; (7) 20 to 25 heated-product sticks; (8) 20 to 25 grams of waterpipe products; and (9) such other quantities as may be prescribed.
q. Consumable means any preparation of various ingredients or substances intended to be consumed with an electronic delivery device or heated product device.
r. Contractor means a person providing services to an operator, receiving services from an operator or supplying items to or purchasing items other than regulated products from an operator.
s. Controlled Consumption Zone means a geographically defined area where consumption of specified regulated products is permitted under licence.
t. Dark Pattern means a design choice in a digital interface that manipulates, deceives, or materially impairs the ability of a user to make free and informed decisions.
u. Digital Product Passport means a standardised electronic record containing information about a product's identity, composition, origin, conformity, and lifecycle.
v. Distance Sales means the sale of regulated products via electronic means, telephone, mail order, or other remote communication where the buyer and seller are not physically present together.
w. Electronic Delivery Device means a device that uses an electrical, electronic, heating, ultrasonic or comparable process to create an aerosol, vapour or emission intended to be inhaled or otherwise introduced into the human body.

x. Emission includes smoke, aerosol, vapour, gas, particles, and substances released during the use of a regulated product.
y. Fulfilment Service Provider means a person who stores, packages, addresses, or dispatches regulated products on behalf of another economic operator without taking ownership.
z. Goods means items intended or appropriate for human consumption, whether packed or unpacked.
aa. Heated Tobacco Product means a tobacco product that is heated without intended combustion to produce an emission containing nicotine and other chemicals for inhalation.
bb. Herbal Smoking Product means a product consisting wholly or partly of vegetable, fungal, or other non-tobacco matter intended to be smoked or heated for inhalation.
cc. Human Consumption includes eating, drinking, chewing, sniffing, smoking, inhaling, injecting, applying to mucosal tissue or otherwise introducing a substance into or onto the body in a manner permitting its absorption.
dd. Illicit Trade means any practice or conduct prohibited by this Regulation relating to the manufacture, import, export, distribution, or sale of regulated products, including counterfeiting, smuggling, tax evasion, and diversion.
ee. Importer means a person introducing products into the national territory, irrespective of ownership.
ff. Ingredient means any substance or material present in a finished product, including additives and substances introduced during manufacture.
gg. Influencer Marketing means any form of commercial communication where a person with a public following promotes or references a regulated product in exchange for payment, free products, or other benefit.
hh. Key Part means a component of a regulated product that is essential for its safety, function, or compliance and has been designated as such.
ii. Manufacturer includes a person who manufactures a product, has it designed or manufactured, and markets it under their own name or trademark, or who substantially modifies a product; it also includes a person who places a name, trademark or distinguishing mark on a product in a manner holding that person out as its manufacturer.
jj. Marketplace means a digital platform enabling multiple traders to offer regulated products to consumers.
kk. Nicotine Delivery means the quantity and rate of nicotine released or absorbed during ordinary or reasonably foreseeable use.
ll. Nicotine Pouch means a portioned tobacco-free product containing nicotine intended for oral placement to deliver nicotine through mucosal tissue.
mm. Novel Product means a regulated product not lawfully supplied in the jurisdiction before a prescribed reference date, or a product whose composition, design, delivery mechanism, or intended use differs materially from previously supplied products.

nn. Operator means any natural or legal person who grows, produces, manufactures, processes, imports, exports, stores, transports, distributes, brokers, advertises, sells, or otherwise deals with regulated products.

oo. Packaging means any material used to contain, protect, present, or identify a regulated product for sale or distribution.

pp. Plain Packaging means standardised packaging with uniform colour, font, and format, devoid of branding, logos, or promotional elements.

qq. Product means a good packaged in a consumer unit.

rr. Promotion includes advertising, sponsorship, product placement, brand sharing, discounts, free distribution, premiums, competitions, loyalty schemes, endorsements, influencer marketing, and any other activity promoting regulated products, including direct and indirect advertising and commercial user-generated content.

ss. Proxy Purchase means the purchase of a regulated product by an adult on behalf of a person prohibited from purchasing it.

tt. Recall means the withdrawal of a regulated product from end-users or consumers.

uu. Regulated Nicotine Product means a product containing nicotine or a nicotine analogue and intended to deliver it to the human body for a non-medical purpose, other than a tobacco product or an authorised medicine.

vv. Regulated Product means any product, preparation, device, component, accessory, or service subject to this Regulation; this includes every ACT good and their accessories.

ww. Responsible Person means a natural person designated by an operator as responsible for regulatory compliance; where required by labour law, such person shall be employed by the operator.

xx. Risk means the combination of the probability of occurrence of harm and the severity of that harm.

yy. Single-Use Device means an electronic delivery device that is pre-filled and not designed to be refilled, regardless of whether its battery can be recharged.

zz. Smoke-Free Generation means a cohort of persons born on or after a specified date who are permanently prohibited from purchasing tobacco products.

aaa. Sponsorship means any form of contribution to an event, activity, individual, or organisation with the aim or effect of promoting a regulated product.

bbb. Standardised Packaging means packaging meeting prescribed requirements for colour, material, shape, size, opening mechanism, and presentation.

ccc. Third-Hand Exposure means exposure to residual contamination from tobacco smoke or vaping aerosol deposited on surfaces, dust, and materials after active smoking or vaping has ceased.

ddd. Tobacco-Based Good includes cigarettes, cigars, cigarillos, pipe tobacco, waterpipe tobacco, roll-your-own tobacco, chewing tobacco, nasal tobacco, tobacco for oral use and any product containing tobacco leaf, plant, seed or extract and intended or appropriate for human consumption.

eee. Tobacco for Oral Use means a tobacco product intended for oral use without smoking or chewing, presented in powder, particulate or portioned form, including Scandinavian snus.

fff. Tobacco-Related Device means a device, other than an electronic delivery device, specifically designed to enable consumption of tobacco, including a heated-tobacco device.

ggg. Traceability means the ability to trace and follow a regulated product, component or substance through all stages of production, processing, distribution, retail, use and, where expressly required, disposal.

hhh. Trader means a person selling or intending to sell regulated products to consumers.

iii. Vapour Inhalation Product means a liquid, gel, solid, powder or other substance intended or appropriate to be aerosolised, vaporised or heated for inhalation, whether or not it contains nicotine.

jjj. Vaping Product means a device or substance that can be used for the consumption of vapour or aerosol via a mouthpiece, whether or not it contains nicotine.

kkk. Waterpipe Product means a preparation intended for consumption by means of a waterpipe, whether or not containing tobacco or nicotine.

lll. Wholesaler means a person selling or intending to sell regulated products to another wholesaler or trader.

mmm. Withdrawal means the removal of a regulated product from the supply chain before it reaches end-users.

CHAPTER 1A — GENERIC BANS AND LIMITATIONS

3. Section 3 — Ban of certain goods

3.1 General prohibition

The growing, manufacture, possession for supply, import, export, transport, storage, advertising, distribution or sale of the following goods is prohibited:
(a) goods listed in Annex IV;
(b) goods containing prohibited ingredients or substances;
(c) counterfeit, adulterated or materially mislabelled goods;
(d) goods lacking a required authorisation, registration or identifier;
(e) goods manufactured under conditions creating an unacceptable risk;
(f) goods whose origin cannot reasonably be determined; and
(g) goods subject to a prohibition or recall order.

3.2 Artificial cannabinoids and rapidly changing substances

Alternative A — Positive list

Only artificial cannabinoids and designed psychoactive substances expressly authorised in Annex I may be supplied.

Alternative B — Negative list

Artificial cannabinoids and designed psychoactive substances listed in Annex I may not be supplied.

Alternative C — Class prohibition

All artificial cannabinoids and designed psychoactive substances intended to imitate or produce effects comparable to cannabis are prohibited unless individually authorised by the ACT Agency.

3.3 Single-use electronic delivery devices

Alternative A — Complete ban

The manufacture, import, distribution, sale and free supply of single-use electronic delivery devices are prohibited, whether or not they contain nicotine.

Alternative B — Restricted authorisation

A single-use electronic delivery device may be supplied only if the ACT Agency is satisfied that:

1. no reasonably practicable reusable alternative provides equivalent functionality;
2. the device participates in an approved producer-responsibility scheme;
3. prescribed collection and recovery targets are met;
4. child, poisoning, fire and environmental risks are adequately controlled; and
5. the authorisation is time-limited.

3.4 Tobacco for oral use and snus

Alternative A — Ban

The placing on the market of tobacco for oral use, including Scandinavian snus, is prohibited.

Alternative B — Regulated market

Tobacco for oral use may be supplied subject to Sections 4 to 13, 19 and 20.

Alternative C — Limited traditional exception

The ACT Agency may authorise a traditionally used oral tobacco product for sale within specified regions or communities, subject to product standards, warnings, age restrictions, maximum nicotine limits and monitoring.

3.5 Nicotine pouches

Alternative A — Ban

The manufacture, import and supply of nicotine pouches are prohibited.

Alternative B — General regulated market

Nicotine pouches may be supplied subject to this Regulation.

Alternative C — Pharmacy-only market

Nicotine pouches may be supplied only through pharmacies [upon prescription] or [following documented professional consultation].

3.6 Vapour inhalation products

Alternative A — Complete prohibition

The manufacture, import, export, transport, sale, distribution, storage and advertising of vapour inhalation products are prohibited.

Alternative B — Non-therapeutic prohibition

Vapour inhalation products may be supplied only as authorised medicines or therapeutic products.

Alternative C — Regulated consumer market

Vapour inhalation products may be supplied in accordance with this Regulation.

3.7 Waterpipe products

Alternative A — Complete prohibition

The manufacture, import, supply, advertisement and commercial consumption of waterpipe products are prohibited.

Alternative B — Licensed establishments only

Waterpipe products may be supplied only by licensed retailers and offered for consumption only in establishments licensed under Section 17.

Alternative C — General regulated market

Waterpipe products may be supplied subject to all tobacco-equivalent requirements of this Regulation.

3.8 Products resembling food, toys or medicines

A regulated product must not be manufactured, packaged or presented so as to resemble:
1. confectionery, sweets, desserts or soft drinks;
2. toys, games, school materials or children’s products;
3. cosmetics or personal-care products;
4. medicines or therapeutic products; or
5. ordinary household products, where the resemblance creates a material risk of accidental consumption, appeal to children or misunderstanding of the product’s nature.

3.9 Dual purpose or dual use products

(1) Products that are intended to be regulated products and intended to be medicine, a medical device or another non-regulated product are prohibited.
(2) Products that are intended to belong to different categories of regulated products are prohibited.
(3) Intended use is to be established taking into account the design, the label, the instructions for use, additional information materials and the publicity of the respective operators and necessarily of the manufacturer.
(4) Any reasonably foreseeable use indicates a certain intended use. However, this presumption is rebutted where the operator does its best to counter the reasonably foreseeable, but unintended use.

CHAPTER 2 — PRODUCT REQUIREMENTS AND STANDARDS

Section 4 — Limitation of Naturally Contained Substances

4.1 Maximum and minimum values

The ACT Agency may establish maximum or minimum values for naturally contained substances, including but not limited to:

- alcohol by volume and per serving;
- THC, CBD, and other cannabinoids;
- nicotine and nicotine analogues;
- tar;
- carbon monoxide;
- aldehydes (formaldehyde, acetaldehyde, acrolein);
- metals (lead, cadmium, arsenic, chromium, nickel);
- volatile organic compounds;
- particulate matter;
- tobacco-specific nitrosamines (TSNAs);
- polycyclic aromatic hydrocarbons;
- psychoactive alkaloids;
- contaminants (pesticides, heavy metals, microbial contaminants);
- residual solvents; and
- any substance materially affecting toxicity, intoxication, or dependence.

4.2 Parameters

Limits may be prescribed by reference to:
(a) concentration per unit volume or weight;
(b) quantity per consumer unit, dose, pouch, stick, activation, or inhalation;
(c) rate of delivery or absorption;

(d) emission under a prescribed testing method;
(e) bioavailability;
(f) reasonably foreseeable maximum exposure; or
(g) cumulative exposure over time.

4.3 Differentiation

The ACT Agency may establish different limits for different product categories, routes of administration, and target populations.

4.4 Periodic review

Values must be reviewed at intervals not exceeding [3] years.

Section 5 — Ban or Limitation of Additives, Flavours and Product Characteristics

5.1 General prohibition

A regulated product must not contain an additive that:
(a) materially increases toxicity, carcinogenicity, mutagenicity, or reproductive toxicity;
(b) materially increases dependence, addictiveness, or the speed of absorption;
(c) facilitates inhalation or masks irritation in a manner increasing consumption;
(d) creates an impression of health, vitality, energy, naturalness, or reduced harm;
(e) is particularly attractive to children or young persons;
(f) colours smoke, aerosol, or vapour;
(g) has not been assessed for safety in the manner in which it is consumed;
(h) creates a risk when heated, burned, or aerosolised;
(i) produces cooling, numbing, or anaesthetic effects masking irritation;
(j) increases the palatability or smoothness of inhalation; or
(k) is prohibited by regulations.

5.2 Prohibited substances (illustrative list)

The following are prohibited in all regulated products:
(a) vitamins or other substances creating an impression of health benefits;
(b) caffeine, taurine, guarana, or other stimulant compounds;
(c) colouring agents for emissions;
(d) substances classified as CMR (carcinogenic, mutagenic, reprotoxic);
(e) diacetyl, acetyl propionyl, and other diketones;
(f) pharmacologically active substances not separately authorised;
(g) substances increasing nicotine uptake or bioavailability;
(h) ammonia or ammonium compounds used to increase free nicotine;
(i) sugars or sweeteners in quantities increasing palatability or combustion by-products;
(j) substances prohibited under Annex V.

5.3 Characterising flavours

Alternative A — Complete prohibition

A regulated product must not have a characterising flavour other than the base product flavour.

Alternative B — Tobacco-only

A regulated product must not have a characterising flavour other than tobacco.

Alternative C — Positive list

Only characterising flavours listed in a positive list maintained by the ACT Agency may be used.

Alternative D — Youth-appeal prohibition

A characterising flavour is prohibited where it is predominantly associated with confectionery, desserts, fruit-fantasy products, soft drinks, toys, or other products primarily attractive to children.

5.4 Flavour accessories and modification devices

A person must not manufacture, import, or supply:
(a) a capsule, insert, filter, mouthpiece, or component intended to impart a prohibited flavour;
(b) a device or software function enabling modification of flavour intensity;
(c) any product enabling circumvention of flavour restrictions.

5.5 Menthol and cooling agents

Alternative A — Complete Prohibition

Menthol and all cooling agents are prohibited in all regulated products.

Alternative B — Targeted Prohibition

Menthol is prohibited in combustible products but permitted in non-combustible products up to [X] mg/unit.

Alternative C — Limitation

Menthol is permitted subject to concentration limits and specific labelling.

5.6 Product characteristics affecting appeal

The ACT Agency may regulate:
(a) product shape, size, and form factor;
(b) device colour, material, and finish;
(c) sound, light, or animation features;
(d) product names and variant designations;
(e) packaging texture and opening mechanism;

(f) any feature increasing appeal to minors.

Section 6 — Safety Features and Product Standards

6.1 General safety obligation

A regulated product must be safe under normal and reasonably foreseeable conditions of use, storage, charging, refilling, transport, maintenance, and disposal. The obligation includes protection against:
(a) poisoning;
(b) contamination;
(c) unintended overdose;
(d) leaching;
(e) leakage;
(f) breakage;
(g) fire or explosion;
(h) electrical or thermal injury;
(i) accidental activation;
(j) activation by children below the age of ten;
(k) unauthorised modification; and
(l) foreseeable misuse, namely by children.

6.2 Specific safety requirements for electronic delivery devices

Electronic delivery devices must:
(a) be protected against overheating, short circuits, battery failure, and accidental activation;
(b) be self-extinguishing and include automatic shut-off after [X] seconds of continuous activation;
(c) maintain authorised temperature, power, and delivery limits, in particular with regard to smoke and vapour;
(d) prevent undisclosed modes that increase emissions or delivery;
(e) be resistant to leakage, breakage, and tampering;
(f) display or communicate prescribed safety information;
(g) bear a unique serial or batch identifier;
(h) comply with prescribed electrical and battery safety standards (other legislation or IEC 62133 or equivalent);
(i) support security updates for a prescribed minimum period;
(j) prevent remote modification beyond authorised parameters;
(k) incorporate child-resistant activation where technically feasible;
(l) be designed without sharps;
(m) include overcharge and over-discharge protection;
(n) use USB-C or equivalent standardised charging interface;
(o) provide battery health monitoring and warning; and

(p) be designed for safe disposal and battery removal.

6.3 Child-resistance requirements

(1) Nicotine-containing liquids, refill containers, and nicotine pouches must be in child-resistant packaging conforming to [ISO 8317 or equivalent].
(2) Electronic delivery devices must incorporate child-resistant activation mechanisms.
(3) Packaging must be tamper-evident.
4) Products must bear the clearly visible warning: "KEEP OUT OF REACH OF CHILDREN."

6.4 Refill system safety

Refill containers and refillable devices must:
(a) have leak-free refilling mechanisms;
(b) prevent skin contact with nicotine-containing liquid during ordinary use;
(c) include instructions for safe refilling and poison response;
(d) comply with applicable poison-prevention packaging standards;
(e) be protected against breakage during normal handling;
(f) be made of materials that do not interact with the consumables; and
(g) limit refill volume to [X] ml per container.

6.5 Heated product device and electronic delivery device safety

(1) Heated product devices and electronic delivery devices must:
(a) not exceed a maximum operating temperature of [X]°C and [Y]°C next to the battery;
(b) automatically shut off after [X] minutes of continuous use or in the event of a short circuit;
(c) incorporate temperature control preventing combustion;
(d) be intended for use only with authorised consumables;
(e) include overheat protection and user warnings;
(f) keep the temperature of smoke or vapour below [Z]°C;
(g) as to their surfaces, be made of bio-compatible and non-allergic materials;
(h) be made of materials that do not leach or otherwise interact with consumables;
(i) reduce to the state of the art level the likelihood of use errors and unintended or intended misuse;
(j) be compatible with the chargers and other items intended to be used with the device;
(k) be pressure-proof, in particular on planes; and
(l) comply with applicable electrical safety standards and legal requirements.

(2) Where heated product devices and electronic delivery devices are prefilled with consumables, the requirements of Subsection 6.7. apply.

6.6 Waterpipe safety and hygiene

Where commercial waterpipe use is permitted:

(a) single-use mouthpieces must be provided;
(b) hoses must be single-use or disinfected after each user;
(c) reusable components must be cleaned and sanitised after each use;
(d) charcoal must comply with emission standards;
(e) continuous carbon monoxide monitoring with audible alarms is required;
(f) ventilation must provide at least [X] air changes per hour;
(g) staff must be trained in CO poisoning recognition and response;
(h) fire safety equipment must be available; and
(i) records of cleaning, product origin, and incidents must be maintained.

6.7 Safety of consumables and of other goods to be consumed

(1) Consumables must:

(a) be tested for pesticides, heavy metals, microbial contamination, mycotoxins, and residual solvents;
(b) comply with the following maximum contaminant limits: …(e.g. reference to food law) ;
(c) be composed solely of the ingredients and substances listed below, whilst the following use limitations apply:

Ingredient / Substance	Not for … (type of consumable)	Not with … (ingredient / substance)

(d) respect the following quantitative limits for active substances: …
(insert a table listing types of consumables vertically and active substances horizontally; insert into the fields the maximum concentration to be respected)

(e) not be composed of more than [X] ingredients and [Y] active substances;

(f) not be composed of ingredients or substances that, when the consumable is used in accordance with its intended purpose, reach temperatures higher than the following:
(insert a table listing types of consumables vertically and ingredients/substances horizontally; insert into the fields the maximum temperature to which the ingredients/substances may be exposed)

(g) not contain chocolate, sweet or fruity flavours;

(h) not contain aromatic ingredients or perfumes;

(i) include, on its label and packaging, serving-size information for edibles;

(j) include, on its label and packaging, onset-time warnings for edibles;

(k) include, on its label and packaging, a clear indication of the intended use and the devices for which it has been developed;

(l) include, on its label and packaging, warning against other use and use with other devices;

(m) bear a series, batch or lot number, a production date and a clearly visible best-to-be-consumed-by date;

(n) bear accurate content labels as to active substances; and

(o) be stored in tamper-evident packaging.

(2) The requirements of Paragraph (1) letters (c) to (n) apply also to nicotine pouches and pouches with other active substances.

(3) The requirements of Paragraph (1) letters (d) and (g) to (n) apply also to natural [khat, coca,] cannabis, marihuana and fungi.

(4) The requirements of Paragraph (1) letters (c) to (n) apply also to preparations of various ingredients or substances other than consumables that include cannabis, marihuana or fungi.

6.8 Alcohol product safety

(1) Alcoholic beverages above [3]% ABV must bear specific health warnings.
(2) Products marketed for rapid consumption (shots, pre-mixed spirits) are subject to additional restrictions.
(3) Containers above [50] ml of spirits must incorporate pour-limiting features or measurement markings.
(4) Alcoholic beverages that also contain caffeine, taurine or other stimulants may not contain more than [5]% alcohol.
(5) Alcoholic products with more than [15]% alcohol shall be protected against opening by children of less than 10 years.

6.9 Conformity assessment

(1) Manufacturers must conduct or obtain prescribed conformity assessment before placing products on the market.
(2) The appropriate conformity assessment is set out by regulation adopted by the Government **OR** ACT Agency. Conformity assessment may include (select from the following subject to the product category and the availability of conformity assessment bodies, accredited laboratories and authority capacities, in accordance with our Handbook 'How to Regulate?'):
(a) type testing by an accredited laboratory;
(b) factory production control assessment;
(c) quality management system audit;
(d) batch testing; and

(e) testing of products on the market.
(3) Where the ACT Agency has not established any conformity assessment, manufacturers must apply the following steps of self-certification (please select):

(a) application of a quality management system covering the entire product development, the manufacturing and the post-market aspects;
(b) application of a risk management system covering at least the risks referred to in this Regulation;
(c) creation of a complete technical documentation, including for components crucial for the good and safe functioning of the product;
(d) use of checklists provided by the ACT Agency;
(e) use of a checklist comprising the requirements and obligations set out by this Regulation;
(f) signing off of all the documents by a qualified person responsible for regulatory compliance; and
(g) signing, by a person authorised to represent the operator, of a public and to be published declaration certifying the conformity of the product with legal requirements set out in this Regulation.

(4) Manufacturers must prepare and retain conformity assessment documents for at least [10] years.

(5) Importers must verify conformity before placing products on the market and must notify the ACT Agency of any non-conforming product.

N.B.: More on conformity assessment to be found in our Handbook 'How to Regulate?' and Chapters D and E of our Cross-sectoral Standard Provisions.

6.10 Incident reporting and corrective action

(1) An operator who knows or reasonably suspects that a product is unsafe or non-conforming must immediately:
(a) stop its supply;
(b) investigate the cause;
(c) notify the ACT Agency within [24/72] hours;
(d) identify affected batches, recipients, and consumers;
(e) take corrective measures (withdrawal, recall, repair, replacement);
(f) preserve evidence; and
(g) cooperate with the ACT Agency investigation.

(2) The ACT Agency may order:
(a) safety warnings;
(b) correction of labelling or instructions;
(c) suspension of supply;
(d) repair, replacement, or refund;
(e) recall;

(f) destruction or safe disposal; and
(g) publication of the safety alert.

Section 7 — Packaging, Labelling and Consumer Information

7.1 Packaging requirements

Regulated products must be supplied in compliant consumer units meeting:
(a) prescribed minimum and maximum sizes;
(b) child-resistance requirements;
(c) tamper-evidence requirements;
(d) material safety requirements;
(e) recyclability or recoverability requirements where prescribed.

7.2 Health warnings — general requirements

(1) Packaging must contain health warnings covering not less than [50/65/75]% of the two largest surfaces.

(2) Warnings must:
(a) be in the official language(s);
(b) use prescribed font, size, colour, and contrast;
(c) not be obscured, removable, or interrupted;
(d) rotate among prescribed sets;
(e) include pictorial warnings where prescribed;
(f) include cessation information; and
(g) include a hotline number or website.

(3) Warnings must cover, in descending order of importance:
(a) dependence and addiction risks;
(b) acute and chronic health risks;
(c) risks to pregnancy and children;
(d) risks arising from driving or operating machinery;
(e) risks to persons exposed to smoke or aerosol;
(f) poisoning and storage risks;
(g) interaction risks; and
(h) disposal and environmental risks.
(4) Packaging must use the following symbols in prescribed size, set out below and in Annex VII:





The car symbol is not needed for tobacco products, vaping liquids without nicotine and vaping devices.

7.3 Product-specific warnings

- Heated tobacco: "Heating tobacco causes cancer, other diseases and infertility. This product is not safe.".
- Nicotine pouch: "Nicotine is highly addictive. This product can harm your gums and cardiovascular system."
- Cannabis edible: "Edible cannabis takes up to 120 minutes to take effect. Do not consume more while waiting. Keep away from children. Do not drive after consumption"
- Alcohol: "Alcohol causes cancer and other diseases. Do not drink during pregnancy. Do not drink and drive." and two images of oral cancer prescribed by the ACT Agency covering at least one third of the front and one third of the back or, in absence thereof, the two largest surfaces.
- Waterpipe: "One waterpipe session can expose you to more smoke than 100 cigarettes. Sharing mouthpieces spreads disease."
- Electronic device: "Improper use, charging, or modification may cause fire, explosion, or chemical burns."

7.4 Mandatory product information

Packaging and, where suitable, the label of the regulated product must state:
(a) all ingredients in descending order of weight;
(b) active-substance content (nicotine mg/ml, THC %, alcohol % ABV);
(c) nicotine delivery per dose;
(d) emissions data where applicable;
(e) manufacturer and importer name and address;
(f) country of origin;
(g) batch or serial number;
(h) date of manufacture and expiry;
(i) storage and safe-use instructions;
(j) contraindications and risk groups;
(k) poison-centre and adverse-event contact details;
(l) disposal and recycling instructions;
(m) product registration number;
(n) unique identifier for traceability;

(o) conformity marking where applicable;
(p) "KEEP OUT OF REACH OF CHILDREN" for nicotine and cannabis products; and
(q) any other prescribed information.

7.5 Prohibited packaging or label elements

Packaging or label must not:
(a) state or imply safety, harmlessness, or health benefits;
(b) is less harmful without an authorised comparative-risk statement;
(c) use terms "natural," "organic," "clean," "detoxifying," "light," "mild," or "smooth" or synonyms thereof without authorisation;
(d) suggest therapeutic or cessation effects without authorisation;
(e) suggest to improve vitality, sexual success, creativity, social status or performance;
(f) is suitable for children, pregnant persons or non-users;
resemble food, confectionery, cosmetics, toys, or medicines;
(g) contain cartoons, mascots, or youth-oriented imagery;
(h) include games, lights, sounds, or interactive features;
(i) state or imply government endorsement;
(k) use environmental claims that are false or unsubstantiated;
(l) include QR codes or links to promotional content; or
(m) contain any misleading element.

7.6 Plain/standardised packaging

Alternative A — Full standardised packaging

All regulated products must be supplied in standardised packaging with:
(a) a uniform prescribed colour (e.g., Pantone 448C) and finish;
(b) standardised dimensions and opening mechanism;
(c) brand name and type and variant names in prescribed typeface, size, and position;
(d) no logos, colours, or decorative elements;
(e) health warnings occupying prescribed percentage; and
(f) only permitted regulatory information.

Alternative B — Category-specific standardised packaging

Standardised packaging applies to (specify categories) as follows: ...

Alternative C — Partial standardisation

Packaging must comply with generic requirements but may retain limited brand elements as follows: ...

7.7 Child-targeted design

Regulated products and their packaging must not:
(a) contain cartoons or pictures of sweets, toys, prominent persons, children, animals or mascots;

(b) have [any] **OR** [more than one] bright colour and more three colours in total[, whilst the brightest colour is to be reserved for warnings];
(c) contain or resemble to games, scores or rewards;
(d) contain or picture entertainment lights, sounds or animations;
(e) have designs resembling toys, confectionery or soft drinks;
(f) school-related imagery;
(g) have designs resembling media or products attractive for children or targeting children; or
(h) other features perceived as predominantly attractive to children.

7.8 Environmental labelling

Packaging must include:
(a) material composition information;
(b) recycling instructions;
(c) producer responsibility scheme identification;
(d) "do not litter" warning for single-use products;
(e) battery disposal instructions for electronic devices; and
(f) carbon footprint information where prescribed.

7.9 Package inserts

The ACT Agency may require inserts concerning:
(a) cessation and treatment;
(b) safe consumption;
(c) poison response;
(d) adverse-event reporting;
(e) safe charging and storage;
(f) pregnancy;
(g) interactions with medicines or other regulated products; and
(h) return, recycling and disposal.

7.10 Digital product information

(1) The ACT Agency may require or permit electronic provision of:
(a) full ingredient lists;
(b) safety data sheets;
(c) instructions for use;
(d) adverse event reporting channels;
(e) recycling instructions; and
(f) recall information.

(2) Electronic information must be accessible via a scannable code on the packaging.
(3) A paper copy must be provided free of charge upon request.

CHAPTER 3 — MARKET ORGANISATION AND OPERATORS

Section 8 — Licensing of Operators

N.B.: This Section could be substantially enhanced by numerous provisions of Chapters D and E of our Cross-sectoral Standard Provisions. See also our Handbook 'How to Regulate?'.

8.1 Licence requirement

No person shall conduct a prescribed activity involving regulated products without a licence issued by the ACT Agency.

8.2 Licence categories

The regulations establish separate licence categories for:
(a) manufacturers (by product category);
(b) importers;
(c) exporters;
(d) wholesalers and distributors;
(e) general retailers;
(f) specialist retailers;
(g) pharmacies (where applicable);
(h) consumption venues;
(i) online/distance sellers;
(j) testing laboratories and conformity assessment bodies;
(k) transport and storage operators;
(l) brokers and intermediaries;
(m) online marketplace operators;
(n) fulfilment service providers;
(o) cultivators (tobacco, cannabis);
(p) disposal and recycling operators; and
(q) advertising and marketing service providers, including influencers.

8.3 Application requirements

(1) An applicant must provide:
(a) legal identity, full legal name, trade name, business registration number, date and place of incorporation, location of corporate headquarters and principal place of business, beneficial ownership, copies of articles of incorporation or equivalent documents, and its corporate affiliates;
(b) directors, officers, and responsible persons;
(c) premises, equipment, and production capacity;
(d) financial statements and banking information;

(e) tax identification, tax and customs compliance certificates;
(f) product categories and expected volumes;
(g) security and inventory control arrangements;
(h) staff competence and training arrangements;
(i) quality management and compliance systems;
(j) insurance or financial security;
(k) environmental management plan;
(l) data protection arrangements;
(m) websites, social media accounts and other communication channels;
(n) criminal record certificates for directors and responsible persons;
(o) evidence of no prior serious regulatory infringements; and
(p) any other prescribed information.

(2) Operators or, in case of legal persons, their directors with power of representation, shall fulfil the following conditions:
(a) having the nationality of …;
(b) being … (e.g. 25) years or older;
(c) not having committed any criminal offence during the last 10 years;
(d) Having not infringed fiscal obligations during 10 years;
(e) not having been listed as deliberately infringing this Regulation in accordance with … (see the provisions on deliberate infringement in Section 35); and
(f) Having undergone a compulsory training for responsible sale offered by the ACT Agency or having nominated a Responsible person who has undergone this training.

8.4 Fitness and propriety

The ACT Agency shall assess:
(a) the applicant's honesty, integrity, and financial soundness;
(b) the competence and qualifications of key personnel;
(c) the absence of relevant convictions within [5/10] years;
(d) the absence of repeated regulatory infringements;
(e) the absence of connections to organised crime;
(f) the adequacy of compliance systems;
(g) the absence of conflicts of interest; and
(h) the applicant's capacity to meet ongoing obligations.

8.5 Risk-tiered licensing

Licences shall be tiered according to risk:
(a) Low-risk activities (e.g., storage of sealed products): simplified notification;
(b) Medium-risk activities (e.g., retail): standard licensing;
(c) High-risk activities (e.g., manufacture, import): enhanced prior approval with ongoing supervision;

(d) Very high-risk activities (e.g., novel products, high-potency cannabis): authorisation with post-market studies.

8.6 Licence conditions

Licences may be subject to conditions concerning:
(a) production methods, technologies, product categories and quantities;
(b) premises and operating hours;
(c) responsible persons and staff competence;
(d) security and inventory control;
(e) age verification;
(f) record-keeping and reporting;
(g) product testing and traceability;
(h) advertising restrictions;
(i) waste management;
(j) insurance or financial security;
(k) management and compliance systems;
(l) independent audit;
(m) data protection;
(n) environmental management;
(o) cooperation with authorities; and
(p) any other condition necessary for public health protection.

8.7 Duration, renewal, and review

(1) Licences are valid for [1/3/5] years.
(2) Renewal requires demonstration of continued compliance. (3) The ACT Agency shall conduct risk-based periodic review of licensees. (4) Licences may be varied, suspended, or revoked in accordance with Section 8.8.

8.8 Suspension, variation, and revocation

(1) The ACT Agency may suspend, vary, or revoke a licence where:
(a) a condition is breached;
(b) the licensee no longer satisfies fitness criteria;
(c) false information was provided;
(d) serious or repeated contraventions occurred;
(e) the activity presents a materially changed risk;
(f) the licensee obstructs inspection;
(g) traceability, tax, or reporting obligations are evaded;
(h) products were supplied to minors;
(i) the licensee is insolvent or dissolved;
(j) a court orders suspension;
(k) immediate action is necessary to prevent harm; or

(l) the initial conditions for licensing were not fulfilled.

(2) Licenses must be withdrawn where the initial conditions are no longer fulfilled or turn out not to be fulfilled from the beginning and in case of more than three infringements of various or the same obligation(s) under this Regulation occurring during 12 months [or 4 infringements occurring during 24 months].

(3) Licenses may be subject to conditions, limited in time or be withdrawn in case of a single, but particularly grave infringement of an obligation under this Regulation. Particular gravity [is given] **OR** [shall be a [rebuttable] presumption] where:
(a) minors or other persons meriting particular protection were put at risk, including by selling close to schools or in areas for which there is a ban;
(b) the official trade schemes and licenses established by this Regulation were by-passed;
(c) the illegality touches a trade volume of more than ... (limitation by entities or value or both);
(d) practices aimed at rendering persons addicted;
…
(e) Licenses may even be suspended or be subject to conditions for a time up to X months in cases where there is just a suspicion of any of the cases mentioned above.

8.9 Transfer of licence

(1) A licence is not transferable without prior approval of the ACT Agency.
(2) In case of death, insolvency, or dissolution of the licensee, the licence expires unless a qualified successor applies within [30/60] days.
(3) Change of ownership or control requires notification and re-application.

8.10 Licence register

The ACT Agency shall maintain a public register of all licences, including:
(a) licensee name and contact;
(b) licence category and scope;
(c) authorised products and activities;
(d) licensed premises or channels;
(e) licence status and conditions;
(f) enforcement history; and
(g) expiry date.

Section 9 — Geographic Monopolies and Controlled Retail Availability

9.1 Principle

A district authority may establish geographically limited retail monopolies for specified regulated products.

9.2 Procedure

Monopolies must be allocated through open, transparent, competitive procedure. A monopoly area may be determined by reference to:
(a) population;
(b) geographic size;
(c) population density;
(d) transport access;
(e) community health indicators;
(f) proximity to prohibition zones; and
(g) illicit-market risk.

9.3 Density limits

There must be no more than [X] retail outlets per [Y] inhabitants or per [Z] square kilometres.

9.4 Distance requirements

No retail outlets are authorised within [X] metres of:
(a) schools and childcare facilities;
(b) playgrounds and youth centres;
(c) hospitals and health facilities;
(d) places of worship;
(e) public transport hubs; and
(f) other locations prescribed by the ACT Agency.

9.5 Operating hours

Operating hours are limited to: …

9.6 Prohibited places

Sales are prohibited in:
(a) educational institutions;
(b) healthcare facilities;
(c) government buildings;
(d) sports facilities during events;
(e) public transport vehicles; and
(f) other prescribed locations.

9.7 Minimum price

The minimum price for a monopoly licence must be calculated per inhabitant or by reference to expected turnover.

9.8 Eligibility

Only licensed and compliant traders may participate.

9.9 Concentration limit

Alternative A — Only (X)
No trader may hold more than (X) geographic monopoly.

Alternative B — Only (X) percent
No trader or connected group may hold more than (X) percent of monopoly areas.

9.10 Consumption-linked fee

Alternative A — Reduction incentive
A portion of the licence fee must be refunded where consumption in the monopoly area decreases by amounts prescribed by the ACT Agency.

Alternative B — Escalating fee
The licence fee must increase progressively where consumption exceeds a benchmark prescribed by the ACT Agency.

Alternative C — No consumption-linked fee
The licence fee must be fixed independently of consumption to avoid incentives to manipulate data or refuse service discriminatorily.

Section 10 — Obligations of Operators

N.B.: This Section could be substantially enhanced by numerous provisions of the Chapters G of our Cross-sectoral Standard Provisions, of the first edition of the Regulatory Institute's Commonwealth and Latin American Legislators' Toolbox and of the second edition of the Regulatory Institute's EU Legislators' Toolbox, both currently still at the work in progress stage.

10.1 General compliance obligations

Operators must:
(a) conduct risk assessment before market placement;
(b) maintain technical documentation and product samples;
(c) implement quality management systems;
(d) ensure batch consistency;
(e) maintain factory production control;
(f) conduct periodic sample testing;
(g) conduct or arrange conformity assessment;
(h) affix required markings and warnings;
(i) ensure all products comply with applicable requirements before supply;
(j) participate in applicable registration and traceability systems;
(k) maintain complete traceability records upstreams and downstreams;
(l) display proof of their registration and licenses at the entrance of their premises;

(m) report to the ACT Agency production, material or design changes within [3/10] working days;
(n) fulfil tax, excise, and customs obligations;
(o) maintain prescribed insurance or financial security;
(p) implement and maintain compliance management systems;
(q) designate a qualified responsible person for regulatory compliance;
(r) train all relevant staff before assignment and periodically thereafter;
(s) cooperate fully with the ACT Agency and enforcement authorities;
(t) preserve records for at least [5/10] years;
(u) study all information provided by the national ACT Agency;
(v) implement corrective measures promptly;
(w) not obstruct, mislead, or provide false information to authorities;
(x) not retaliate against whistleblowers or cooperating staff;
(y) comply with environmental management obligations;
(z) implement data protection measures;
(aa) ensure contractors comply with applicable obligations;
(bb) provide spare parts for [X] years after last production;
(cc) offer repair services or information;
(dd) participate in producer responsibility schemes;
(ee) protect their stock from robbery and physical deterioration;
(ff) maintain rigorous book-keeping control on all incoming and outgoing goods so as to be able to determine their stock at any time;
(gg) verify the identity of all suppliers and clients [buying more than [X];
(hh) report to the ACT Agency all – by quantity, type or other conditions – suspicious demand for products and suspected non-compliance with this regulation;
(ii) verify that commercial trade partners hold a license in accordance with this regulation or, in case of trade partners located abroad, inform the ACT Agency on the commercial contact with this trade partner;
(jj) register data of their trade partners for their own records and [in the goods registration scheme foreseen in Section 12] **OR** [the ACT traceability scheme foreseen in Section 13], whilst these data must include:

i. when the customer is a natural person, information regarding its identity, including full name, trade name, business registration number (if any), applicable tax registration numbers (if any) and copy or scanning of his or her official identification;
ii. when the customer is a legal person, information regarding its identity, including full name, trade name, business registration number, date and place of incorporation, location of corporate headquarters and principal place of business, applicable tax registration numbers, copies of articles of incorporation or equivalent documents, its corporate affiliates, names of its directors and any designated legal representatives, including the representatives' names and verification of their official identification; and
iii. a description of the intended use and intended market of sale of the ACT

goods.

10.2 Incident reporting

(1) An operator must notify the ACT Agency without undue delay of:
(a) death or serious injury linked to a product;
(b) poisoning;
(c) battery fire or explosion;
(d) material deviation in nicotine, THC or alcohol content or deviation in other active substances;
(e) contamination or adulteration;
(f) significant packaging or warning failure;
(g) recall or withdrawal triggered by the operator or one of its commercial partners;
(h) theft or diversion of significant stock;
(i) evidence on counterfeiting; and
(j) any other serious incident [prescribed by the ACT Agency].

(2) The obligations of paragraph (1) (a) to (g) apply also with regards to products owned or in possession of third parties where the operator has obtained information on the incident.

10.3 Retail-specific obligations

Traders additionally must:
(a) verify age of purchasers;
(b) implement responsible sale policies;
(c) refuse supply in prescribed circumstances;
(d) maintain structural separation of regulated products;
(e) not display products contrary to requirements;
(g) not sell outside licensed premises or hours;
(h) implement self-service prohibitions;
(i) maintain temperature, humidity and other prescribed storage conditions;
(j) not sell damaged, expired, or recalled products;
(k) display required warnings and information;
(l) operate prescribed age-verification systems, namely by verifying the ID card of persons looking like adolescents;
(m) record and report refused sales;
(n) not sell unpackaged or incorrectly labelled products;
(o) prevent proxy purchases;
(p) not provide free samples except as expressly permitted;
(q) comply with quantity limits;
(r) implement intoxication refusal policies;
(s) maintain incident and complaint records;
(t) only buy goods from registered wholesalers and verify the registration of the goods prior to the purchase;

(u) not sell to persons whom they know do not consume the ACT products themselves;
(v) record customer purchases to enforce regulated product sales limits;
(w) not sell more than one/two/three consumer unit(s) per day to the same person;
(x) not sell to persons who are in an altered state of consciousness or drunk;
(y) inform persons repeatedly in an altered state of consciousness or drunk or showing signs of addiction or consuming ACT products whilst pregnant or in presence of minors on private or public institutions, where to seek help for their repeated state of altered consciousness or perceived addiction;
(z) [respect the prohibition zones] **OR** [not sell outside the licensed premises];
(aa) not sell unpacked goods;
(bb) not sell entities smaller or bigger than the regulated consumer units as defined above;
(cc) respect the authorised price bandwidth and in particular the mandatory minimum price per consumer unit;
(dd) verify that the consumer units are correctly labelled;
(ee) verify that tax and excise obligations have been fulfilled and, if not, fulfil them immediately themselves;
(ff) report to authorities in case of any suspicion on illicit trade, tax or excise or product irregularity, and therein in particular insufficient warning text and pictures on packaging;
(gg) place warning text panels with deterring pictures identical to the ones on the packaging next to the ACT products and at a well visible place in their shop, whilst these panels shall have at least the following size … and characteristics (minimum text, font size, type and size of deterring pictures); and
(hh) not sell via internet, phone or otherwise at distance or via automatic vending machines.

10.4 Online and distance sales obligations

Online sellers additionally must:
(a) implement robust age verification at point of sale and delivery;
(b) display all required warnings and information before purchase;
(c) use adult signature-required delivery;
(d) prevent delivery to schools, youth facilities, or prescribed locations;
(e) retain verification and transaction records;
(f) prevent bulk purchasing and proxy purchasing;
(g) not use subscription models without explicit re-confirmation;
(h) implement returns and recall procedures;
(i) display licence number and regulatory information;
(j) not use dark patterns or manipulative design;
(k) not use consumption data for marketing; and
(l) comply with cross-border distance sales restrictions.

10.5 Digital-platform duties

(1) An online marketplace enabling transactions involving regulated products must:

(a) verify trader identity and licence status;
(b) verify product registration;
(c) display prescribed warnings;
(d) implement age-restricted access and purchase controls;
(e) act expeditiously on lawful notices;
(f) detect repeated unlawful listings;
(g) preserve prescribed evidence;
(h) suspend repeat offenders; and
(i) report systemic risks to the ACT Agency.
(2) A general-purpose intermediary is not responsible or liable solely because its service is used unlawfully where it neither knew nor reasonably ought to have known and complied promptly with applicable duties.

10.6 Supply chain due diligence

(1) Operators must exercise due diligence to ensure their supply chain is free from:
(a) illicit products;
(b) forced labour;
(c) environmental destruction;
(d) tax evasion;
(e) corruption; and
(f) human rights abuses.
(2) The diligence due is proportional to the operator's size in terms of employees, turn-over and profit. For operators belonging to a group of legal persons, the size of the group is decisive.
(3) The ACT Agency may prescribe specific due diligence requirements for high-risk supply chains and for large operators or groups.

10.7 Environmental producer responsibility

(1) Manufacturers and importers of electronic delivery devices, pods, cartridges and batteries must participate in an approved producer-responsibility scheme providing:
(a) free collection by all participants, regardless of whether the item was acquired for the specific participant;
(b) safe storage and transport;
(c) safe recycling and disposal;
(d) public information campaigns;
(e) reporting;
(f) recovery targets; and
(g) payment of full net scheme costs.
(2) Retailers must accept used products without charge.

10.8 Outsourcing limitations

(1) An operator outsourcing compliance tasks remains fully responsible for compliance.

(2) Outsourcing must not:
(a) delegate or dilute responsibility;
(b) alter the operator's obligations;
(c) prevent effective supervision;
(d) reduce data protection standards; or
(e) impede access by authorities.
(3) The ACT Agency may prohibit or subject to conditions the outsourcing of critical compliance functions.

10.9 Responsible person

(1) Each operator must designate a responsible person for regulatory compliance.
(2) The responsible person must:
(a) be a natural person formally employed under labour law;
(b) have appropriate qualifications and training;
(c) have sufficient authority within the organisation;
(d) be accessible to authorities;
(e) ensure timely reporting; and
(f) sign compliance declarations.
(3) The responsible person may be held personally liable for failures within their remit.

10.10 Compliance department

Operators exceeding thresholds prescribed by the ACT Agency must establish an independent compliance function with:
(a) a high-level head reporting directly to the board or being a member thereof;
(b) sufficient resources and authority;
(c) direct access to all relevant information;
(d) independence from commercial functions;
(e) periodic independent reporting to the ACT Agency; and
(f) whistleblower protection mechanisms.

10.11 Staff compliance

Operators must:
(a) verify prescribed fitness requirements of staff;
(b) train staff in responsible sale and whistleblower protections;
(c) suspend a staff member from regulated duties where reasonably necessary during investigation;
(d) not retaliate against staff reporting non-compliance;
(e) maintain signed training and compliance declarations;
(f) verify every six months that all their employees have a clean criminal record and have not been declared to have deliberately infringed this Regulation by the ACT Agency and lay-off employees which do not fulfil these conditions, whilst criminal convictions for negligence only count where they relate to book-keeping, tax and excises and

infringements under this Regulation;
(g) lay-off employees for whom the ACT Agency has stated a deliberate infringement of this Regulation and temporarily suspend the work contract for those whom the ACT Agency has opened an investigation of suspicion of deliberate infringement;
(h) lay-off employees who do not respect the obligations incumbent on operators;
(i) inform and train all their staff on these obligations, on the sanctions to be expected in case of non-compliance with these obligations, and on the provisions on whistle-blowing protection set-out in this Regulation;
(j) verify that their staff have undergone the training for responsible sale offered by the ACT Agency prior to recruitment and conduct re-training every second year after recruitment; and
(j) establish and implement a self-monitoring plan or quality system ensuring and verifying compliance with these obligations.

Section 11 — Structural Separation in Mixed Trading Outlets

11.1 Principle of separation

Regulated products in mixed trading outlets must be kept in a separate, clearly controlled area restricting access by minors (“regulated area”) under intense supervision prohibiting the access of minors.

11.2 Regulated area

The regulated area must be:
(a) located remotely from entrances, checkouts, confectionery, toys, and children's goods;
(b) not visible from outside the premises;
(c) staffed by trained personnel;
(d) subject to access control where prescribed;
(e) clearly signposted with health warnings; and
(f) separated by physical barriers where prescribed.

11.3 Display alternatives

Alternative A — Complete display ban
Regulated products must not be visible to consumers before a lawful purchase request.

Alternative B — Adult-only display
Products may be visible only within an access-controlled adult-only area.

Alternative C — Limited standardised display
Only a plain-text price list in prescribed format may be displayed.

11.4 Self-service access

Self-service access to regulated products is prohibited.

11.5 Vending machines

Vending machines for regulated products are [prohibited / restricted to adult-only locations with age verification].

11.6 Conflict of rules

Where structural separation rules conflict, the rule providing greater protection against youth access and incidental exposure prevails.

Section 12 — Registration, Notification and Authorisation of Products

N.B.: This Section could be substantially enhanced by numerous provisions of Chapters D and E of our Cross-sectoral Standard Provisions for Regulation and by numerous tools listed in Chapters D and E of our work-in-progress Commonwealth and Latin American Legislators' Toolbox or of the parallel EU Legislators' Toolbox. The tools of these toolboxes are widely, but not totally overlapping.

12.1 Pre-market notification

(1) No manufacturer or importer shall place a regulated product on the market without prior notification to the ACT Agency.
(2) Notification must be submitted at least [3/6] months before intended market placement.
(3) Notification must include:
(a) manufacturer and importer identity;
(b) product description and category;
(c) complete ingredient and material list with quantities;
(d) toxicological data on ingredients and emissions;
(e) nicotine/THC/alcohol or other active substance content and delivery data;
(f) manufacturing process and quality control;
(g) packaging, labelling, and warning specimens;
(h) intended use and target population;
(i) foreseeable misuse scenarios;
(j) environmental and waste information;
(k) conformity assessment evidence;
(l) stability and shelf-life data;
(m) child-safety assessment;
(n) marketing plan summary;
(o) post-market surveillance plan; and
(p) any other information prescribed by the ACT Agency.

12.2 Authorisation for novel and high-risk products

(1) Novel products and products presenting elevated risk require authorisation before market placement.
(2) Authorisation may be granted only where, in addition to the fulfilment of the information requirements set out in Subsection 12.1:
(a) the product complies with all applicable requirements and standards;

(b) risks have been reduced so far as [reasonably] possible **OR** practicable;
(c) the product will not materially increase initiation by minors or non-users;
(d) manufacturing quality can be ensured;
(e) traceability and recall are practicable;
(f) claims are substantiated;
(g) the applicant can ensure post-market monitoring; and
(h) marketing is consistent with public health protection.

12.3 Conditional and provisional authorisation

(1) The ACT Agency may grant time-limited or conditional authorisation where:
(a) urgent public health need exists, namely where a product is very likely to be substantially less harmful than the other products of that category;
(b) full data is not yet available;
(c) ongoing monitoring can manage residual risk; and
(d) the benefit outweighs the risk.
(2) Conditions may include:
(a) post-market studies;
(b) restricted distribution channels;
(c) enhanced warnings;
(d) sales volume limits;
(e) periodic re-evaluation;
(f) restrictions on flavours or package sizes;
(g) environmental recovery obligations; and
(h) automatic expiry.

12.4 Product modification notification

Registration or authorisation must be updated before a material change concerning:
(a) composition;
(b) nicotine, THC or alcohol content or content of another active substance;
(c) delivery or emission profile;
(d) device power or software;
(e) flavour;
(f) manufacturing process;
(g) package size;
(h) packaging, labelling, warning or instructions; or
(i) product name or presentation.

12.5 Product register

The ACT Agency shall maintain a public register of all registered and authorised products.

12.6 Fees

The ACT Agency may levy proportionate fees for:
(a) notification processing;

(b) authorisation assessment;
(c) annual registration maintenance;
(d) modification assessment;
(e) post-market surveillance;
(f) testing and inspection; and
(g) processing of non-compliances.

Section 13 — National Traceability and Anti-Illicit-Trade Scheme

13.1 Establishment

The ACT Agency shall establish an electronic traceability system for all prescribed regulated products.

13.2 Unique identifiers

(1) Each prescribed unit packet and aggregate package must bear an irremovable unique identifier.
(2) The identifier must permit determination of:
(a) manufacturer, manufacturing facility and, in case of imported products, of the importer and of the legal representative of the manufacturer based in (your jurisdiction), including for all of them their physical address, post boxes and electronic communication channels;
(b) date and place of manufacture;
(c) product description, category, and batch;
(d) intended market;
(e) quantity manufactured;
(f) customs entry point;
(g) successive commercial recipients;
(h) shipment dates and routes;
(i) retail sale data (pseudonymised);
(j) withdrawal and recall events; and
(k) destruction records.
(3) Where an entity is divided into smaller entities, each smaller entity must bear an identifier linked to the original entity.
(4) Where entities are aggregated, the aggregate identifier must link to each contained entity.

13.3 Data storage and independence

(1) Traceability data must be stored by independent third parties approved by the ACT Agency.
(2) Data must be kept separate from other commercial data.
(3) Data must be accessible to the ACT Agency at all times.
(4) Data must be protected against alteration and unauthorised access.
(5) Data retention period: [5/10] years.

13.4 Security features

Packages must bear visible and invisible security features including:
(a) holograms;
(b) forensic markers;
(c) digital authentication codes;
(d) tamper-evident seals; and
(e) other features prescribed by the ACT Agency.

13.5 Device serialisation

Reusable electronic delivery and heated-product devices intended to be reprocessed must bear registered serial numbers linked to the traceability system.

13.6 Prohibited conduct

A person must not:
(a) remove, obscure, counterfeit, or reuse an identifier unless this is necessary for safe disposal;
(b) possess or supply a product bearing a false identifier;
(c) knowingly supply outside the recorded lawful chain;
(d) falsify traceability data;
(e) interfere with a tracking system;
(f) possess or supply products without required identifiers; or
(g) circumvent traceability requirements.

13.7 Anti-illicit-trade measures

(1) The ACT Agency may require:
(a) tax stamps or excise marks;
(b) supply chain due diligence;
(c) suspicious transaction reporting;
(d) production capacity disclosure;
(e) raw material tracking;
(f) equipment registration;
(g) customs cooperation protocols;
(h) intelligence sharing;
(i) enforcement operations coordinated with other authorities;
(j) mandatory reporting of suspected illicit trade by other authorities
(k) destruction of seized illicit products;
(l) publication of illicit trade statistics; and (m) international cooperation on illicit trade.
(2) The ACT Agency:
(a) must/may create whistleblower incentives and whistleblower and witness protection schemes;
(b) must create an illicit trade alert portal;
(c) may establish international cooperation regarding the tracking of illicit trade.
(d) may authorise and mandate the use of blockchain or distributed ledger technology for enhanced transparency and immutability of traceability data.

CHAPTER 4 — INCENTIVES, CONSUMPTION AND AVAILABILITY

Section 14 — Cessation support

14.1 Cessation support obligations

(1) The ACT Agency shall ensure availability of:
(a) free or subsidised cessation services;
(b) quitlines (telephone and digital);
(c) nicotine replacement therapy access;
(d) counselling and behavioural support;
(e) pharmacological support where appropriate;
(f) peer support groups;
(g) digital cessation tools; and
(h) specialised services for vulnerable populations.
(2) The ACT Agency may require operators to contribute to cessation funding through levies.
[(3) Cessation information must be included in all health warnings and product information.]

14.1 Incentives for citizens

(1) A person participating in the traceability scheme who does not purchase a regulated product for [one] year may receive a reduction in a prescribed health-insurance contribution.
(2) A person under [18/21] years who participates lawfully in the scheme may receive an annual allowance for each year in which no regulated product is purchased or consumed.
(3) Participation in an approved cessation programme may be treated as non-purchase or reduced consumption for incentive purposes.
(4) Where consumer-level traceability is considered disproportionate, incentives may instead be based on:
(a) participation in cessation programmes;
(b) verified clinical indicators;
(c) voluntary self-reporting supported by counselling; or
(d) other privacy-preserving methods.
(5) An incentive must not:
(a) result in denial of essential health care;
(b) penalise relapse;
(c) disclose consumption data to employers;
(d) discriminate unlawfully; or
(e) create a coercive requirement to participate in consumer-level tracking.

Section 15 — Cannabis or fungi social clubs

15.1 — General conditions

A cannabis or fungi social club may operate where:
(a) it is constituted as a non-profit association;
(b) cultivation is limited to [X] plants per member;
(c) distribution is limited to [X] grams per member per month;
(d) no advertising or promotion occurs;
(e) premises are not visible from public areas;
(f) strict inventory records are maintained;
(g) no consumption by minors is permitted;
(h) no making available to non-members occurs;
(i) consumption is stopped where the member loses control;
(j) safe transport home of persons unable to drive or use public transport is ensured;
(k) the club participates in a monitoring programme established by the ACT Agency; and
(l) the club is licensed by the ACT Agency.

15.2 — Licensing

(1) To obtain a license from the ACT Agency, these clubs shall be duly registered associations with no more than [X] members. At the time of application, at least three members must have undergone the training for responsible sale offered by the ACT Agency for the specific type of consumption.
(2) Regarding the procedure and other general rules of licensing, Section 8 applies.

15.3 — Membership

(1) Only adult persons with permanent residence in … (jurisdiction) may become members of the clubs. All members reside within [X] km.
(2) The membership is limited to [X] adults.
(3) The clubs shall register their members in the database of the ACT Agency.
(4) The ACT Agency shall verify that no person is a member of several clubs.

15.4 — Inspection

The ACT Agency may inspect the facilities at any time without any warrant and including by undercover agents.

15.5 — Ongoing obligations

(1) Social clubs must continuously respect the general conditions set out in Subsection 15.1.
(2) Social clubs must report incidents, non-conforming and unsafe products to the ACT Agency within 24 hours.

Section 16 — ACT Prohibition zones

16.1 — Places and perimeters

Within the following places and a perimeter of [50/100/200/500] metres, the sale, advertising and consumption of prescribed regulated products is prohibited:
(a) zones declared to be non-ACT zones by the owner or the responsible natural or legal person;
(b) commercial centres;
(c) kindergartens, schools, and institutions of higher education (including those in the private sector) and students accommodation centres;
(d) health, day-care, elderly, family, children, educational, vocational, training, sport, recreational, cultural and religious centres;
(e) sport events;
(f) public transport facilities, except in zones clearly labelled as ACT zones;
(g) public transport planes, ships or vehicles including taxis and similar vehicles;
(h) petrol stations;
(i) markets;
(j) playing grounds;
(k) shops also selling goods appropriate for children;
(l) beaches [during holiday seasons];
(m) national roads and other high-risk transport corridors; and
(n) further public places determined by the ACT Agency or local authorities.

16.2 — Responsible persons

(1) The natural or legal person in charge of the respective place or zone must:
(a) display notices indicating that ACT consumption is prohibited in the area;
(b) supervise and carry out measures to ensure that the prohibition is respected;
(c) request the offending persons to cease the offence or to leave the area; and
(d) where the offending person refuses to do so, report to the police / a law enforcement officer and allow s/he to inspect the area.
(2) Where a responsible natural or legal person cannot be identified, local authorities must take over the responsibility set out in paragraph (1).

Section 17 — Responsible service

17.1 Alcohol premises

Licensed premises serving alcohol must:
(a) train all staff in responsible service;
(b) implement intoxication refusal policies;
(c) provide free drinking water;
(d) offer an equal number of non-alcoholic alternatives at reasonable prices;
(e) display standard drink information;
(f) not promote rapid consumption (drinking games, shots promotions);

(g) not serve visibly intoxicated persons;
(h) facilitate safe transport home;
(i) maintain incident records;
(j) cooperate with police on disorder prevention;
(k) implement CCTV where prescribed;
(l) comply with noise and nuisance requirements; and
(m) offer at least 10 non-alcoholic choices of beverages at a price 50% lower than the cheapest alcoholic beverage of any volume and the cheapest alcoholic beverage of the same volume.

17.2 Mobile or street alcohol delivery

(1) Mobile or street delivery of alcohol is limited to licensed operators.
(2) Licensed delivery operators must fulfil the obligations of Subsection 17.1 (a) to (g) and (i) to (m).
(3) The sale for on-the-spot consumption of beverages exceeding [5/10/15] percent alcohol by volume is limited to one drink per 3 hours.
(4) Serving alcohol after [11 p.m./1 a.m.] is prohibited or subject to special authorisation.

17.3 Waterpipe premises

Waterpipe premises must:
(a) admit adults only;
(b) use registered products;
(c) maintain product packets for inspection;
(d) implement ventilation and carbon-monoxide monitoring;
(e) make available hygienic mouthpieces and hoses, one per client;
(f) display warnings; and
(g) record incidents.

Section 18 — Consumption in public indoor and specified outdoor areas

18.1 Indoor prohibition

Smoking tobacco, cannabis, herbal or waterpipe products, and using an electronic delivery or heated-product device, is prohibited in indoor areas open to the public and in workplaces. The prohibition applies whether or not the product contains nicotine or tobacco and whether or not a visible emission is produced.

18.2 Limited smoking areas

Alternative A — No exception

No public indoor smoking or vaping area is permitted. An area is also considered to be public where it is accessible to members of a club or association.

Alternative B — Specialised consumption venues only

Only facilities whose principal licensed purpose is controlled consumption may permit indoor use, provided no person under [18] years is present.

Alternative C — Limited exception

No public indoor smoking or vaping area is permitted. An area is also considered to be public where it is accessible to members of a club or association. However, a club, association, bar or restaurant may reserve a separated area of not more than [one-quarter/one-third] of the public surface, enclosed by smoke-proof walls and double doors and subject to prescribed ventilation and worker-protection requirements. It must ensure that no person under [18] years is present.

18.3 Vehicles

Smoking tobacco, cannabis, herbal or waterpipe products, and using an electronic delivery or heated-product device ("vaping") in a motor vehicle while a person under [18] years is present is prohibited.

18.4 Outdoor areas

The ACT Agency and local authorities may designate as smoke- and aerosol-free:
(a) school and hospital grounds;
(b) playgrounds;
(c) public transport stops;
(d) queues;
(e) event venues;
(f) beaches;
(g) outdoor restaurant areas;
(h) entrances, windows and air intakes; and
(i) other areas where exposure or youth normalization presents material risk.

18.5 No ventilation defence

Ventilation, filtration or physical separation does not by itself constitute compliance with this Section.

Section 19 — General use and sales limitations

19.1 Minimum age

(1) The sale or supply of a regulated product or regulated delivery device to a person under [18/21] years is prohibited.
(2) Consumption of regulated products in ad hoc or permanent groups comprising persons under the age of [X] is forbidden.
(3) Operators must use government-issued photo ID or approved digital verification for age verification.

19.2 Generational prohibition

A trader must not sell tobacco products, herbal smoking products or cigarette papers to a person born on or after [1 January 2009], irrespective of that person's age at the time of sale.

19.3 Proxy purchase

Purchasing or attempting to purchase a regulated product for a person prohibited from purchasing it is prohibited.

19.4 Secondary exposure

A person must not smoke or use an aerosol product in a manner exposing another person in a vehicle, building or other enclosed facility.

19.5 Driving and machinery

A person must not drive or operate a vehicle, aircraft, vessel, drone or dangerous machine while impaired by alcohol, cannabis or another psychoactive regulated product.

Alternative A — Fixed threshold

A blood, breath or oral-fluid threshold prescribed by the ACT Agency applies.

Alternative B — Impairment standard

Use is prohibited where the person's capacity is materially impaired.

Alternative C — Combined standard

Use is prohibited where the person's capacity is materially impaired or where a blood, breath or oral-fluid threshold prescribed by the ACT Agency is trespassed.

19.6 Consumption prior to driving and machinery operation

Consumption of alcohol or cannabis (products) is forbidden when it is planned or not unlikely to be necessary to drive or to operate vehicles, planes, drones, ships, robots or machines. Driving or operating vehicles, planes, ships or machines 12 hours after having consumed alcohol or cannabis(products) is forbidden[, unless the alcohol concentration in the blood stays below 0.05 g/dl.

19.7 Consumption during pregnancy

(1) The ACT Agency and local authorities must warn against consumption of regulated products during pregnancy and must provide support by counselling and health services.
(2) The ACT Agency and local authorities may prohibit in specified high-risk circumstances, the consumption of regulated products by pregnant persons.
(3) Operators must not serve regulated products to visibly pregnant persons.

19.8 Product mixing

The ACT Agency may prohibit or restrict:
(a) combining alcohol and stimulant substances;
(b) combining nicotine and cannabis in one product;
(c) multi-compartment products enabling simultaneous consumption;
(d) products designed to facilitate excessive or rapid consumption; and

(e) other combinations presenting disproportionate risk.

19.9 Third-hand smoke and aerosol

The ACT Agency may prescribe requirements for:
(a) cleaning of surfaces in former smoking areas;
(b) ventilation standards for multi-unit housing;
(c) disclosure of smoking history in rental properties; and
(d) protection of children in vehicles and enclosed spaces.

19.10 Enforcement

(1) Operators and local authorities must regularly conduct test purchasing programmes.
(2) The results of test purchases must be recorded and reported to the ACT Agency.
(3) Staff who do not respect the obligations set out in this Regulation must receive retraining and must be laid-off in case of repetition.
(4) Repeated non-compliances by operators must result in licence suspension.
(5) Repetition is given where the same type of non-compliance occurs … (e.g. twice) per 12 months or where there are within 12 months [X] cases of non-compliance under this Section.

CHAPTER 5 — COMMERCIAL COMMUNICATION AND INDUSTRY INFLUENCE

Section 20 — Advertisement

20.1 Principle

Alternative A — Comprehensive prohibition

All advertising, promotion, and product placement of regulated products is prohibited.

Alternative B — Restricted communication

Advertising, promotion, and product placement of regulated products is permitted only in prescribed adult-only channels and subject to this Section.

Alternative C — Differential model

Advertising, promotion, and product placement of regulated products is prohibited, while alcohol advertising is permitted subject to this Section.

20.2 Conduct included

Advertising, promotion, and product placement include:
(a) use of internet, social media, television, radio, print media and outdoor surfaces and activities;
(b) paid or supported influencer content;

(c) testimonials and endorsements;
(d) brand sharing and stretching;
(e) direct calls and electronic messages;
(f) free distribution and samples;
(g) discounts, coupons and happy hours;
(h) competitions, lotteries and loyalty schemes;
(i) paid search placement;
(j) preferential marketplace placement;
(k) geolocation marketing;
(l) commercial user-generated content;
(m) promotional features embedded in devices;
(n) games, rewards, scores, lights or social-sharing functions;
(o) promotional data notifications; and
(p) marketing of components or non-regulated products intended indirectly to promote regulated products.

20.3 Required warnings under restricted-advertising model

(1) Advertisement, promotion and product placement must prominently state the risks and warnings mandatorily to be displayed for the respective regulated product. Provisions on the minimum surface to be covered by warnings apply.

(2) Where no specific provisions apply to the regulated product, advertisement, promotion and product placement must state
(a) the general risks of consumption;
(b) the risks of driving and machinery operation;
(c) the risks for pregnancy and fertility;
(d) the risks of cancer and mutagenic effects;
(e) addiction risks;
(f) the address of an ACT Agency information website; and
(g) prescribed cessation information.

20.4 Placement restrictions

Advertisement, promotion and product placement must not:
(a) be directed at children or young persons;
(b) depict persons under [25] years;
(c) appear within the prohibition zones set out in Section 18.
(d) appear in media with more than [10/20] percent child audience;
(e) be placed jointly with advertisement, promotion and product placement for ordinary consumer goods;
(f) use cartoon, gaming or youth-cultural imagery; or
(g) be shown between … (specified hours).

20.5 Prohibited representations

It is prohibited to:

(a) suggest health or therapeutic benefits without authorisation;
(b) suggest improved success, vitality, creativity, sexual attractiveness, therapeutic effects, stimulant or sedative effects, higher performance, more wellbeing, liberty, more social or sexual success, more creativity, or higher degrees of awareness or to present regulated products as means to solve personal problems.
(c) portray consumption by minors;
(d) present abstinence or moderation negatively;
(e) imply government approval;
(f) use environmental claims that are false or unsubstantiated;
(g) refer to the absence of tobacco, smoke, nicotine or other elements; or
(h) refer to “natural” or “organic”.

20.6 Comparative-risk claims

(1) A reduced-risk or reduced-exposure claim may be made only if separately authorised.
(2) Authorisation requires evidence that the claim:
(a) accurately presents absolute and relative risk;
(b) is unlikely to mislead concerning addiction or dual use;
(c) is unlikely materially to increase initiation;
(d) distinguishes complete switching from dual use;
(e) remains supported by current evidence; and
(f) is subject to post-market monitoring by the operators involved.

20.7 Non-commercial representation

Representation of consumption in documentary, artistic, journalistic or storytelling contexts must be limited to what is reasonably necessary in the specific documentary, artistic or story-telling context. Any presentation of a brand is forbidden unless essential to the context. Containers or packages of regulated products must be chosen in such a way that shapes or colours which are characteristic for a certain brand or manufacturer are avoided.

20.8 Connected-device data

Data generated by a regulated product or application must not be used to:
(a) advertise regulated products;
(b) increase frequency or quantity of use;
(c) personalise prices;
(d) operate reward programmes;
(e) target vulnerability or dependence; or
(f) rank users socially.

20.9 Extraterritorial promotion

A person who arranges, funds or controls prohibited content is responsible notwithstanding that publication occurs outside the jurisdiction, where the content is directed at persons within the jurisdiction.

20.10 — Digital advertising and platform responsibilities

(1) Social media platforms must:
(a) prohibit paid promotion of regulated products;
(b) prohibit commercial user-generated content promoting regulated products;
(c) implement age verification for regulated product content;
(d) prohibit viral marketing campaigns;
(e) prohibit gamification of consumption; and
(f) report aggregate data on regulated product content to authorities.
(2) Online platforms, including social media, hosting regulated product content must:
(a) verify advertiser identity and authorisation;
(b) ensure age-gating for advertising content;
(c) remove unlawful advertising within [24/48] hours of notification;
(d) maintain advertising archives for [X] years;
(e) provide advertising data to authorities on request;
(f) implement automated detection of prohibited content;
(g) not use algorithmic amplification for regulated product content;
(h) prohibit influencer marketing to audiences with >[X]% minors;
(i) label all commercial content clearly; and
(j) prohibit targeted advertising based on health data, age, or vulnerability.

20.10 — Point-of-sale restrictions

(1) Point-of-sale advertising is [prohibited / restricted to plain text price lists].
(2) No promotional materials may be visible from outside premises.
(3) No price promotions, multi-buy offers, or loss-leader pricing is permitted.
(4) No placement near confectionery, toys, or children's products is permitted.
(5) No sampling or tasting at point of sale except is permitted.

20.11 — Brand stretching and brand sharing

(1) Use of a regulated product brand, name, logo, or design on non-regulated products is prohibited.
(2) Use of a non-regulated product brand on regulated products is prohibited.
(3) Co-branding arrangements are prohibited.

20.12 — Child-oriented products

The sale and advertisement, promotion or product placement of food, toys or other products intended for children or adolescents whose design imitates regulated products is prohibited.

20.13 — Clothing and merchandise

The sale of clothing or merchandise [for minors] bearing regulated-product brands, logos or recognisable package designs is prohibited.

20.14 — Games

Games that normalise or promote regulated-product consumption are prohibited [where accessible to minors].

Section 21 — Sponsorship prohibition

Sponsorship is prohibited for:
(a) sporting events, teams, institutions and programmes;
(b) cultural events, institutions and programmes;
(c) research and educational events, institutions and programmes;
(d) health events, institutions and programmes;
(e) political events, parties, institutions, campaigns and programmes;
(f) media productions;
(g) charitable events, institutions and programmes;
(h) youth events, institutions and programmes;
(i) community events;
(j) digital content and streaming;
(k) e-sports and gaming;
(l) music events, institutions and programmes; and
(m) any event accessible to minors.

Section 22 — Ban of products evoking regulated products

22.1 — Clothing

The production, import, merchandising or sale of clothing [for minors] with images of regulated products or with logos or brand names of operators providing regulated products is forbidden.

22.2 Food, toys and other products for minors

The merchandising, sale of food, toys, and other products intended for minors whose designs mimic regulated products is forbidden.

22.3 Games

Games, including online games, referring to regulated products are forbidden.

Section 23 — Protection of public health policy

23.1 General Principles

(1) In setting and implementing public health policies with respect to regulated products, public authorities shall act to protect these policies from commercial and other vested interests of the regulated product industry.

(2) Public authorities shall:

(a) interact with the industry only where strictly necessary for regulation and pursuit of regulatory goals;
(b) ensure transparency of all interactions;
(c) not accept partnerships or voluntary agreements as substitutes for regulation;
(d) not allow industry self-regulation;
(e) require disclosure of industry lobbying;
(f) reject industry-funded research in policy development;
(g) implement cooling-off periods;
(h) prohibit industry participation in delegation to international meetings;
(i) not grant preferential access; and
(j) protect officials from industry pressure.
(3) A public register of all meetings between officials and industry representatives must be maintained.

23.2 Corporate social responsibility prohibition

(1) Operators must not undertake corporate social responsibility activities with the aim or effect of promoting their products or influencing policy.
(2) Public authorities must not endorse or participate in industry CSR activities.
(3) Industry-funded "education" programmes in schools are prohibited.
(4) Operators and their organisations must disclose in advance:
(a) meetings and communications with public officials;
(b) participants and subject matter thereof;
(c) position papers and other policy materials;
(d) financial expenditure;
(e) political or financial contributions to organisations;
(f) indirect representation through consultants or associations; and
(g) funding of research, media, consumer or patient organisations and think tanks.
(4) Paragraph (3) letters (e), (f) and (g) apply also with regard to activities abroad.
(5) To the extent concerned, public institutions must publish corresponding records.

23.3 Conflicts of interest

(1) Members and staff of the ACT Agency, Scientific ACT Committee and review bodies must disclose, for themselves, their spouses, and parents or descendants of both themselves and their spouses:
(a) financial interests;
(b) employment and consultancy relationships;
(c) gifts or hospitality received;
(d) stipends or research funding received; and
(e) other relevant relationships during the preceding [5] years.
(2) Conflicts must be managed by recusal, restriction, divestment or exclusion.

23.4 Cooling-off period

A [senior] official may not accept employment, remuneration or a mandate from a regulated operator for [2/5] years after leaving office, unless an independent ethics body determines that no conflict exists.

23.5 Industry-funded research

Industry-funded research may not be relied upon in regulatory decision-making unless:
(a) funding and conflicts are fully disclosed;
(b) the protocol was registered before data collection;
(c) methods and results are independently reviewable;
(d) raw data are accessible subject to lawful protections; and
(e) the ACT Agency evaluates the evidence independently.

CHAPTER 6 — PRIVATE CONDUCT

Sections 24 — Private imports for personal consumption

24.1 Principle

Alternative A — Prohibition

Private import of regulated products is prohibited.

Alternative B — Traveller allowance

An adult traveller may personally import quantities prescribed below or by the ACT Agency after an absence of at least [24/48] hours.

Alternative C — Licensed distance import

Private import may occur only through a registered remote seller and customs-cleared delivery.

24.2 Traveller limits

The following limits apply:
(a) alcohol: [X] litres containing not more than [Y] grams of alcohol;
(b) cannabis: [X] grams;
(c) tobacco: [X] cigarettes, [Y] cigarillos or cigars or [z] grams and (not more than one of the three categories **OR** with 1g tobacco being equivalent to one cigarette or cigarillo and one cigar being equivalent to 4 cigarettes or cigarillos);
(d) vaping liquid: [X] millilitres;
(e) nicotine pouches: [X] consumer units; and
(f) heated-product sticks: [X] consumer units.

24.3 Conditions

A lawful private import requires:
(a) passage through the “products to declare" lane of an official border post;

(b) declaration in advance or at first contact;
(c) proof of age;
(d) compliant packaging and warnings;
(e) payment of duties;
(f) no reselling; and
(g) cooperation with inspection.

24.4 Excess quantities

Alternative A
Any excess quantity is confiscated without compensation.

Alternative B
An unintentional excess not exceeding [X] percent may be released upon payment of duties and an administrative charge.

Alternative C
The entire shipment is confiscated where any limit is exceeded [by X percent].

Section 25 — Private production

25.1 Principle

Alternative A — Prohibition
Private production of regulated products is prohibited.

Alternative B — Limited personal production
Production for the personal consumption of the producer and prescribed adult household members is permitted within the limits prescribed by the ACT Agency.

Alternative C — Permit system
Private production requires a simplified permit.

25.2 Limits

The regulations adopted by the ACT Agency may limit:
(a) the land area used for fungi, tobacco or cannabis;
(b) the number of fungi, khat, coca, tobacco or cannabis plants;
(c) the annual harvest of these plants;
(d) the maximum stored quantity of these plants;
(d) the annual alcohol production, the alcohol concentration and the combination of quantity and concentration;
(e) the extraction methods;
(f) the transfer to household members; and
(g) the equipment used.

25.3 Safety and notification

Private producers must:

(a) label containers with producer, date and quantity;
(b) notify production or harvest;
(c) keep monthly stock records;
(d) prevent access by children;
(e) permit inspection on reasonable grounds; and
(f) not use dangerous extraction or distillation methods.

25.4 No commercial supply

Privately produced goods must not be sold, advertised, exchanged for value or supplied outside the permitted household group.

Section 26 — Private possession

26.1 Principle

Possession of regulated products for private use is lawful only within limits prescribed below or by the ACT Agency and subject to lawful acquisition.

26.2 Limits

(1) Limits include:
(a) [200] grams of tobacco;
(b) [200] cigarettes or cigarillos;
(c) [50] cigars;
(d) [20] grams of cannabis;
(e) [50] grams of marijuana;
(f) [50] grams of coca or khat;
(g) [100] litres of wine, cider or beer;
(h) [10] litres of other alcoholic beverages;
(i) [X] millilitres of vaping liquid;
(j) [X] nicotine pouches; and
(l) [X] heated-product sticks.
(2) For tobacco products, a combined threshold of [300] grams applies, with one cigarette or cigarillo being equivalent to 1 gram and one cigar being equivalent to 4 grams.

26.3 Larger stocks

A person wishing to hold a larger lawful quantity must notify the ACT Agency and provide an inventory at prescribed intervals.

26.4 Presumption of commercial possession

Possession exceeding [X] times the private limit creates a rebuttable presumption of possession for commercial purposes.

26.5 Proportionate response

Minor excess possession without evidence of supply should ordinarily be addressed through:

(a) warning;
(b) confiscation of excess quantity;
(c) education or treatment referral; or
(d) a proportionate administrative sanction or other measure.

26.6 Social intervention

(1) Teachers, health professionals, social workers, employers and persons responsible for vulnerable persons must, within their lawful remit:
(a) offer support where problematic consumption is suspected;
(b) provide information;
(c) refer persons to medical or specialised services; and
(d) avoid stigmatisation and unjustified punitive action.
(2) Teachers, health professionals, social workers, employers and persons responsible for vulnerable persons must also inform the responsible authorities of illegal commercial activities related to regulated products.

CHAPTER 7 — MONITORING, GOVERNANCE AND ENFORCEMENT

Section 27 — Monitoring, Surveillance and Research

27.1 National monitoring system

(1) The ACT Agency shall establish and maintain a comprehensive monitoring system covering:
(a) consumption patterns by product, demographics, and geography;
(b) initiation rates and age of first use;
(c) dependence and cessation rates;
(d) morbidity, mortality, and disability-adjusted life years;
(e) poisoning, injury, and adverse events;
(f) second-hand and third-hand exposure;
(g) illicit trade volumes and patterns;
(h) market developments and product innovations;
(i) advertising exposure and effectiveness;
(j) compliance rates;
(k) enforcement activity;
(l) environmental impact;
(m) economic costs of harm;
(n) health inequalities;
(o) industry conduct and interference; and
(p) international trends.
(2) At intervals not exceeding [3] years, the ACT Agency shall compare the regulation of principal product classes by reference to:

(a) morbidity and mortality;
(b) dependence;
(c) acute injury;
(d) risks to non-users;
(e) initiation and cessation;
(f) switching and dual use;
(g) youth appeal;
(h) illicit-market effects;
(i) environmental effects;
(j) inequalities; and
(k) evidential uncertainty.
The resulting report must recommend whether controls should be strengthened, reduced, differentiated or maintained.

27.2 Product-incident surveillance

The ACT Agency shall operate a system recording:
(a) acute poisonings (nicotine, alcohol, cannabis, CO);
(b) battery fires and explosions;
(c) burns and electrical injuries;
(d) leaking of liquids and leaching of chemicals;
(e) accidental ingestion by children;
(f) adverse effects of product combinations;
(g) device malfunctions;
(h) contamination events;
(i) allergic reactions;
(j) long-term health effects; and
(k) environmental incidents.

27.3 Mandatory operator reporting

Manufacturers and importers shall submit:
(a) annual sales data by product, flavour, and channel;
(b) consumer preference data;
(c) marketing expenditure;
(d) product modification reports;
(e) adverse event reports;
(f) recall and withdrawal reports;
(g) environmental recovery data;
h) supply chain information; and
(i) any other prescribed information.

27.4 Independent research

(1) The ACT Agency shall commission independent research on:

(a) health effects of regulated products;
(b) effectiveness of regulatory measures;
(c) industry conduct;
(d) emerging risks;
(e) cessation interventions;
(f) environmental impact; and
(g) health economics.
(2) Industry-funded research must be disclosed and independently evaluated before reliance.

27.5 Independent evaluation

An independent evaluation of this Regulation must be conducted every [5] years, assessing:
(a) effectiveness against objectives;
(b) proportionality;
(c) distributional effects;
(d) unintended consequences;
(e) enforcement adequacy;
(f) regulatory gaps;
(g) international alignment; and
(h) cost-effectiveness.

Section 28 — Obligations, Tasks and Powers of the ACT Agency

28.1 General functions

The ACT Agency must:
(a) administer and enforce this Regulation;
(b) register and license operators and products;
(c) establish and manage traceability systems;
(d) conduct inspections and market surveillance;
(e) monitor markets, consumption, and harms;
(f) coordinate enforcement with other authorities;
(g) develop standards and technical specifications;
(h) provide training and capacity building to operators, including by developing a prototype self-monitoring plan or quality system ensuring and verifying compliance;
(i) conduct public education and awareness campaigns;
(j) support cessation and treatment;
(k) cooperate nationally and internationally, the latter namely with regard to enforcement;
(l) report to the legislature;
(m) evaluate this Regulation;
(n) maintain registers and databases;
(o) issue guidance and interpretations;

(p) manage complaints and alerts via a dedicated portal permitting two-ways confidential communication;
(q) protect whistleblowers and witnesses;
(r) respond to emergencies;
(s) conduct risk assessment;
(t) publish enforcement data;
(u) levy fees for all procedures it is involved in, including enforcement procedures, by … (ordinance, regulation adopted in accordance with ...); and
(u) perform any other function prescribed.

28.2 Investigative powers

The ACT Agency may, with regard to operators and third parties:
(a) enter and inspect business premises at any reasonable time, even without a warrant;
(b) enter and inspect vehicles, vessels, and aircraft, even without a warrant;
(c) inspect records, documents, electronic systems, and products;
(d) take samples for testing;
(e) make test purchases anonymously;
(f) require information and documents;
(g) summon witnesses;
(h) seek search warrants;
(i) request information from payment, internet, and telecommunications providers;
(j) acquire information from third parties;
(k) process and exchange data;
(l) conduct surveillance under judicial authorisation;
(m) use undercover agents;
(n) inspect online markets;
(o) conduct mystery shopping;
(p) use drones and satellite imagery under authorisation;
(q) use artificial intelligence for detection and analysis;
(r) conduct stress tests and real-time audits;
(s) require warrants to get access to private premises, equipment, and personnel;
(t) seize and detain products, documents, and evidence;
(u) require cessation of activities pending investigation;
(v) interview staff and operators;
(w) require production of financial records;
(x) conduct forensic analysis;
(y) arrest persons and impose financial sanctions in case that cooperation obligations are not fulfilled;
(z) supervise the internet communication or telecommunication (meta-data or even content) in a personalised or generic way;
(aa) exchanging data with other authorities, courts, natural or legal persons or other jurisdictions;

(bb) exercise any other power necessary for effective enforcement.

28.3 General compliance powers

The ACT Agency may:
(a) issue advice, warnings, and guidance;
(b) issue improvement notices with deadlines;
(c) accept enforceable undertakings as substitute for prescribed action;
(d) impose product conditions;
(e) require additional testing;
(f) require compliance plans;
(g) appoint independent monitors, to be paid by the economic operator;
(h) require financial security;
(i) suspend specified operations;
(j) prohibit use of premises or equipment;
(k) require training;
(l) order correction of labels or advertising;
(m) require recall or withdrawal;
(n) impose temporary bans;
(o) require and execute the destruction of non-compliant or ownerless products or of products for which the origin of production or manufacturing is unknown or uncertain;
(p) issue fixed penalty notices;
(q) impose administrative fines;
(r) suspend or revoke licences;
(s) publish enforcement decisions;
(t) issue compliance certificates;
(u) grant exemptions and derogations;
(v) issue binding interpretations;
(w) ban or limit the use of substances,
(x) set minimum or maximum prices for regulated products;
(y) confiscate and destroy goods or means serving to produce illegal products;
(z) forbid the use of premises or establishments for storage of goods or production of products;
(aa) close plants and other premises temporarily, in case of suspected massive infringement of this Regulation, and to that end seal of facilities, confiscate data or objects;
(bb) close plants and other premises definitively, in case of proven massive infringement of this Regulation, and to that end seal of facilities, confiscate or destruct data or objects;
(cc) retain shipments;
(dd) request securities as guarantee for the fulfilment of obligations;
(ee) confiscate objects, rights or money as means to enforce financial obligation or sanction;
(ff) confiscate objects, rights or money obtained directly or indirectly from practices infringing this Regulation;

(gg) delegate enforcement tasks by means of public or private law;
(hh) oblige local enforcement authorities to fulfil minimum resource requirements for the fulfilment of obligations under this Regulation; and
(ii) establish parameters for determining how many full-time equivalents (FTE) are needed for enforcement at the level of local enforcement authorities.

28.4 Digital enforcement powers

The ACT Agency may, also with regard digital operators not connected to regulated products:
(a) require removal of unlawful listings;
(b) order blocking of unlawful content, subject to safeguards;
(c) require preservation of digital evidence;
(d) require suspension of repeat-offender accounts;
(e) require to verify traders;
(f) request domain suspension through judicial procedures;
(g) use automated analytical tools;
(h) require access to algorithmic systems;
(i) order correction of digital content;
(j) require data portability for enforcement; and
(k) issue takedown orders, including for entire websites.

28.5 Emergency powers

(1) Where a product or activity presents a serious and urgent risk, the ACT Agency may issue an interim order:
(a) prohibiting or restricting manufacture, import, supply, or use;
(b) imposing temporary standards or warnings;
(c) requiring testing, notification, withdrawal, or recall;
(d) directing detention or disposal;
(e) requiring public warnings;
(f) suspending licences; or
(g) closing premises.
(2) An order expires after [90] days unless revoked, extended once for [90] days, or replaced by regulations.
(3) Reasons and review rights must be published.
(4) The ACT Agency must review the order continuously and revoke or narrow it when no longer necessary.

28.6 Artificial intelligence and technology use

(1) The ACT Agency may use AI, machine learning, and advanced analytics for:
(a) detection of non-compliance patterns;
(b) risk-based targeting of inspections;
(c) analysis of market data;

(d) identification of illicit trade;
(e) monitoring of online markets;
(f) predictive analytics;
(g) image recognition for product identification;
(h) natural language processing for advertising monitoring; and
(i) data matching and cross-referencing.
(2) Use of AI must comply with:
(a) data protection requirements;
(b) transparency obligations;
(c) human oversight requirements;
(d) non-discrimination requirements;
(e) accuracy validation;
(f) audit trails; and
(g) right to human review of significant decisions.

28.7 Reporting and transparency

The ACT Agency must:
(a) publish an annual enforcement report;
(b) publish enforcement statistics;
(c) publish guidance and interpretations;
(d) maintain public registers;
(e) publish risk assessments;
(f) publish inspection results;
(g) publish recall and safety alerts;
(h) respond to information requests;
(i) publish meeting agendas and minutes;
(j) analyse the data generated by the traceability scheme and provide both the raw data and the analysis to the authorities in charge of taxes, excises and customs; and
(k) maintain a public website with all relevant information.

28.8 Training and capacity building

The ACT Agency must:
(a) provide initial and ongoing training for enforcement staff;
(b) develop training materials;
(c) conduct joint training with other authorities;
(d) participate in international training programmes;
(e) maintain competence records;
(f) conduct peer reviews;
(g) ensure by internal procedures that all staff is independent from interests of operators; and
(h) exchange staff with other authorities.

Section 29 — International Cooperation

29.1 Bilateral and multilateral cooperation

The ACT Agency may:
(a) conclude cooperation agreements with foreign authorities;
(b) exchange information and intelligence;
(c) conduct joint investigations;
(d) provide and receive mutual legal assistance;
(e) participate in international organisations;
(f) align standards with international bodies;
(g) recognise foreign certificates and approvals;
(h) coordinate recalls and safety alerts;
(i) cooperate against illicit trade;
(j) participate in peer reviews;
(k) exchange staff and experts;
(l) establish joint expert committees and data exchange needed for that purpose;
(m) provide technical assistance;
(n) participate in joint procurement;
(o) share traceability data; and
(p) coordinate enforcement actions.

29.2 WHO FCTC implementation

The ACT Agency must, to the extent compatible with the domestic legal order, implement obligations under:
(a) WHO Framework Convention on Tobacco Control;
(b) Protocol to Eliminate Illicit Trade in Tobacco Products; and
(c) relevant COP decisions.

29.3 International standards alignment

The ACT Agency must:
(a) participate in international standardization (ISO, IEC, WHO);
(b) align testing methods with international standards;
(c) participate in international pharmacovigilance networks;
(d) contribute to international research consortia;
(e) align traceability with international systems;
(f) participate in rapid alert systems; and
(g) contribute to international databases.

29.4 Mutual recognition

(1) The ACT Agency may recognise foreign certificates, test reports, and approvals where:
(a) the foreign system provides equivalent protection;
(b) reciprocity is ensured;

(c) the foreign authority is competent;
(d) information sharing is possible; and
(e) public health is not compromised.
(2) Recognition may be conditional or limited to specific product categories.
(3) Where a foreign authority has prohibited or recalled a product on serious public-health grounds, the ACT Agency must assess without undue delay whether corresponding domestic action is necessary. The ACT Agency must inform the foreign agency of any measures taken and must call for being informed of new findings in that matter.

29.5 Cross-border enforcement

(1) The ACT Agency may:
(a) request enforcement assistance from foreign authorities;
(b) provide enforcement assistance to foreign authorities;
(c) enforce or requesting local enforcement authorities to enforce foreign measures provided;
(d) participate in joint investigation teams;
(e) share enforcement data;
(f) coordinate border controls;
(g) conduct joint operations;
(h) recognise and enforce foreign decisions; and
(i) extradite offenders where applicable.
(2) Assistance may only be provided where:
(a) reciprocity or a legal basis exists;
(b) rule of law requirements and domestic principles of legality will be respected by the foreign authorities;
(c) confidentiality is protected;
(d) personal data receives adequate protection; and
(e) the action is proportionate.

29.6 Extraterritorial enforcement

(1) The ACT Agency may take action against foreign operators targeting the domestic market.
(2) Actions may include:
(a) blocking access to non-compliant websites;
(b) requiring removal of listings;
(c) imposing penalties on domestic intermediaries;
(d) notifying foreign authorities;
(e) requesting takedown from hosting providers;
(f) customs interception;
(g) financial sanctions; and
(h) public warnings.

29.7 Cooperation of courts and attorney generals

(1) Courts and attorney generals may provide assistance to foreign courts and attorney generals concerning:
(a) evidence;
(b) witnesses;
(c) recognition of enforcement;
(d) restraint and confiscation;
(e) extradition; and
(f) service of documents.
(2) Assistance may only be provided where:
(a) reciprocity or a legal basis exists;
(b) rule of law requirements and domestic principles of legality will be respected by the foreign authorities;
(c) confidentiality is protected;
(d) personal data receives adequate protection; and
(e) the action is proportionate.

29.8 International traceability

The ACT Agency may establish interoperability between domestic and foreign traceability systems, subject to security and data-protection requirements.

Section 30 — Intra-State, Scientific and Technical Cooperation

30.1 Inter-agency cooperation

The following bodies must cooperate with the ACT Agency:
(a) tax and customs authorities;
(b) police and other law enforcement authorities;
(c) courts and prosecutors;
(d) health and pharmaceutical authorities;
(e) consumer protection bodies;
(f) environmental and waste authorities;
(g) education authorities;
(h) transport authorities;
(i) competition authorities;
(j) data protection authorities;
(k) financial regulators;
(l) telecommunications regulators;
(m) local governments;
(n) poison centres;
(o) testing laboratories;
(p) research institutions;
(q) social services;

(r) occupational health and safety authorities; and
(s) any other prescribed body.

30.2 Information sharing obligations

(1) Agencies shall share information necessary for enforcement.
(2) Information sharing must comply with data protection law.
(3) Confidentiality obligations do not prevent sharing for enforcement purposes.
(4) Shared information may be used only for authorised purposes.

30.3 Joint operations

(1) The ACT Agency may conduct joint operations with other agencies.
(2) Joint operations may include:
(a) coordinated inspections;
(b) joint investigations;
(c) multi-agency task forces;
(d) shared intelligence;
(e) combined border controls;
(f) joint training; and
(g) shared databases.

30.4 Research cooperation

(1) The ACT Agency may cooperate with:
(a) universities;
(b) research institutes;
(c) international research bodies;
(d) WHO collaborating centres;
(e) national health institutes; and
(f) independent laboratories.
(2) Research priorities must be set by the Scientific ACT Committee.
(3) Industry-funded research must meet independence criteria.
(4) The ACT Agency may invite foreign institutions and international organisations to participate as observers or advisers.
(5) State-funded universities and research institutions must make relevant expertise available to the ACT Agency on request, subject to academic independence and applicable cost arrangements.

Section 31 — Scientific ACT Committee

31.1 Establishment and composition

(1) A Scientific ACT Committee is established as an independent advisory body.

(2) Up to [X] members must be appointed by the Government **OR** the ACT Agency through an open procedure based on scientific competence and independence. The procedure must comprise a two-months public call for interest.
(3) The Committee shall include expertise in:
(a) epidemiology;
(b) toxicology;
(c) addiction medicine;
(d) psychiatry and psychology;
(e) pharmacology;
(f) public health;
(g) economics and taxation;
(h) environmental health;
(i) child and adolescent health;
(j) law and regulation;
(k) behavioural science;
(l) chemistry and product analysis;
(m) engineering and device safety;
(n) data science;
(o) consumer and community perspectives; and
(p) industry analysis.
(4) The ACT Agency may invite representatives of foreign institutes and universities and representatives of international organisations to become temporary observers or permanent members.
(5) [The government must also nominate the chair of the Committee.] **OR** [The members shall elect the chair of the Committee.]

31.2 Working methods

(1) The ACT Agency must provide the secretariat.
(2) The ACT Agency must elaborate the draft rules of procedure which shall become applicable [after approval by the responsible minister] / [adoption by the Committee]. The rules of procedure must in particular deal with the processing of conflicts of interest.
(3) The members of the Committee shall obtain a (tax-exempted) daily allowance for each meeting day and X days per year for domestic work. The level daily allowance is Y and must be annually adapted following the Z index / must be periodically adapted by decision of the responsible minister.
(4) Members are obliged to keep confidentiality except in cases where they become aware of undue influences, corruption or falsification of findings. Before alerting the public in these cases, they shall inform the minister in charge unless they have reasons to believe that the minister is involved in the irregularities or that the disclosure would thereby become ineffective

31.3 Functions

The Committee must:

(a) assess absolute and relative risks of products;
(b) assess dependence, toxicity, and product appeal;
(c) examine initiation, cessation, switching, dual use, and relapse;
(d) advise on product classification and designation;
(e) review limits and standards;
(f) assess emerging products and novel substances;
(g) advise before designation or emergency action;
(h) identify research priorities;
(i) publish annual horizon-scanning reports;
(j) review major industry submissions independently;
(k) assess comparative risk across product categories;
(l) advise on environmental impact;
(m) evaluate effectiveness of regulatory measures;
(n) advise on international developments;
(o) assess novel delivery mechanisms;
(p) review testing methodologies;
(q) advise on youth appeal and marketing effects; and
(r) provide opinions on request.

31.4 Independence and conflicts

(1) The members of the Committee are independent from any instruction.
(2) Members must declare interests annually and two weeks before each meeting. Members must disclose in particular, for themselves, their spouses, and parents or descendants of both themselves and their spouses:
(a) financial interests relating to the future or the preceding [5] years;
(b) employment and consultancy relationships relating to the future or the preceding [5] years;
(c) gifts or hospitality received during the preceding [5] years;
(d) stipends or research funding received during the preceding [5] years; and
(e) other relevant relationships during the preceding [5] years.
(3) Conflicts must be managed by recusal, restriction, divestment or exclusion. **OR** Members with conflicts must recuse themselves. **OR** The ACT Agency shall decide on the temporary or permanent exclusion of the member or observer with full discretionary power.
(4) Members must not have received industry funding within [5] years.
(5) The Committee's opinions must be published.
(6) Minority opinions must be recorded.

31.5 Comparative risk assessment

At intervals not exceeding [3] years, the Committee shall conduct a comprehensive comparative assessment of all regulated product categories by reference to:
(a) mortality and morbidity;
(b) dependence potential;

(c) acute injury;
(d) risks to non-users;
(e) initiation and cessation;
(f) switching and dual use;
(g) youth appeal;
(h) illicit market effects;
(i) environmental effects;
(j) inequalities; and
(k) evidential uncertainty.

Section 32 — Central Alert Portal, Whistleblower and Witness Protection

32.1 Alert portal

(1) The ACT Agency must operate:
(a) an electronic portal permitting anonymous reports;
(b) a confidential hotline;
(c) a system allowing bilateral communication without revealing identity;
(d) accessible reporting channels for persons with disabilities;
(e) multilingual reporting;
(f) mobile application reporting; and
(g) integration with other alert systems.
(2) Reports may concern:
(a) product safety risks;
(b) regulatory infringements;
(c) illicit trade;
(d) falsification of data, records and documents;
(e) corruption;
(f) environmental harm;
(g) advertising violations;
(h) sales to minors;
(i) workplace safety; and
(j) any other matter within scope.

32.2 Whistleblower protection

(1) Employees or other persons working for operators, contractors of operators and staff working for contractors of operators are exempted from their confidentiality obligations under labour or contractual law and any other legal provisions or contracts obliging them to keep information confidential provided that they act in good faith when disclosing information on possible infringement of legal obligations set-out in this Regulation. Good faith is to be presumed where the primary motivation is the disclosure of the infringement of this regulation or a connected law.

(2) Protected disclosures include:

(a) past, present, or likely future infringements;
(b) product safety risks;
(c) falsification of data, records or documents;
(d) illicit trade;
(e) corruption or interference;
(f) retaliation;
(g) concealment or destruction of evidence;
(h) misuse of funds; and
(i) breach of public health obligations.
(3) A disclosure remains protected where the reporter's reasonable belief is later shown to be incorrect.

32.3 Prohibition of retaliation

(1) Dismissal, demotion, harassment, blacklisting, loss of benefits, or other retaliation is prohibited.
(2) Where adverse action follows a protected disclosure, the employer bears the burden of proving the action was unrelated.
(3) Interim protection must be available pending resolution.

32.4 Remedies for whistleblowers

A whistleblower may obtain:
(a) reinstatement;
(b) compensation for lost income and damages;
(c) interim protection orders;
(d) legal assistance;
(e) psychological support;
(f) relocation or witness protection;
(g) identity change in extreme cases;
(h) reintegration programmes; and
(i) any other appropriate remedy.

32.5 Rewards

The ACT Agency may award a whistleblower up to [X]% of recovered penalties or prevented loss, subject to a prescribed cap.

32.6 Confidentiality

(1) The identity of whistleblowers must be protected.
(2) No person may attempt to identify a whistleblower.
(3) Breach of whistleblower confidentiality is an offence.

32.7 Evidence preservation

With the whistleblower’s consent, a statement may be formally recorded for use in later proceedings notwithstanding subsequent withdrawal, subject to fair-trial requirements.

[Where the whistle-blower agrees to it, the statement of whistle-blower must be recorded in presence of … (e.g. a judge in charge of instructions); such a statement can be used in all state procedures, including criminal and civil law procedures, even where the whistle-blower "withdraws" it.]

32.8 Witnesses

Subsections 32.2 to 32.7 apply also to witnesses.

Section 33 — Financial Mechanisms

33.1 ACT Agency grants

Within its budget, the ACT Agency may support:
(a) best-practice guidance;
(b) peer review of operators, of authorities and of other actors;
(c) independent research;
(d) prevention and cessation programmes;
(e) treatment and recovery;
(f) harm-reduction services;
(g) environmental recovery;
(h) technical assistance for operators and authorities;
(i) independent conformity-testing capacity; and
(j) transition to non-regulated business models.

33.2 Excise duties

The ACT Agency may suggest to the legislature to impose excise duties by reference to:
(a) quantity, volume, or weight;
(b) alcohol, THC, nicotine or other active substance content;
(c) product value;
(d) emissions;
(e) environmental impact;
(f) comparative risk;
(g) packaging type;
(h) single-use vs. reusable; and
(i) any other prescribed criterion.

33.3 Public health levy

(1) A levy may be imposed on manufacture, import, or wholesale of regulated products.

(2) Revenue must fund:
(a) administration and enforcement;
(b) independent research;
(c) cessation and treatment;
(d) compensation of whistleblowers;

(e) environmental remediation;
(f) community programmes;
(g) international cooperation; and
(h) public education.

(3) Regulated industries must not control allocation.

(4) A cross-subsidisation mechanism may be established whereby revenues from higher-risk products fund:
(a) cessation services;
(b) harm reduction;
(c) environmental remediation;
(d) research; and (e) community support.
(5) Annual audited accounts must be published.

33.4 Cost recovery

The ACT Agency may charge fees for:
(a) licences for operators;
(b) product registration;
(c) product authorisation;
(d) testing;
(e) inspection;
(f) recall administration;
(g) certification;
(h) enforcement attributable to non-compliance;
(i) information requests;
(j) appeals; and
(k) any other prescribed service or mandatory activity.

33.5 Independent implementation fund

(1) The ACT Agency may feed an independent implementation fund with the revenues referred to in Subsections [33.2,] 33.3 and 33.4.
(2) The governance rules must be approved by the Government.
(3) The fund may not be used for expenditures other than those referred to in this Section.
(4) The fund must undergo annual audit and is subject to annual public reporting.

Section 34 — Supervision of Authorities

34.1 Independent review

The ACT Agency, Scientific Committee, and enforcement authorities shall be reviewed by [an independent body] at least every [2] years.

34.2 Peer review

(1) Enforcement authorities shall participate in peer review by authorities of other jurisdictions.
(2) Peer reviews shall assess:
(a) effectiveness;
(b) consistency;
(c) resource adequacy;
(d) compliance with procedures;
(e) training;
(f) use of powers;
(g) decision quality; and
(h) cooperation.

34.3 Continuous improvement

(1) All authorities must implement continuous improvement processes.
(2) Annual performance indicators must be published.
(3) Benchmarking against comparable authorities must be conducted.

34.4 Complaints against authorities

(1) The Government must establish a mechanism for complaints against the ACT Agency and enforcement authorities. It may entrust the Court of Auditors to investigate such complaints.
(2) Complaints must be investigated independently.
(3) Results must be published.

Section 35 — Sanctions and Accompanying Measures

35.1 General principles

(1) Sanctions must be:
(a) effective;
(b) proportionate;
(c) dissuasive;
(d) consistent;
(e) transparent;
(f) subject to review;
(g) non-discriminatory; and
(h) applied without undue delay.

(2) Relevant factors include:
(a) seriousness and duration;
(b) actual and potential harm;
(c) number and vulnerability of affected persons;
(d) intentional, reckless or negligent character;

(e) economic benefit;
(f) cooperation;
(g) remedial action;
(h) previous infringements;
(i) obstruction or concealment; and
(j) operator size and capacity.

(3) Sanctions for unlawful private possession may include:
(a) warning;
(b) confiscation;
(c) administrative fine;
(d) education or treatment;
(e) community service; and
(f) criminal penalties only for serious, repeated or supply-related conduct.

(4) Possession for commercial purposes of unregistered, untraceable, counterfeit or prohibited products may be sanctioned by:
(a) seizure;
(b) confiscation;
(c) destruction;
(d) administrative fine;
(e) licence suspension;
(f) closure; and
(g) prosecution in serious cases.

35.2 Criminal penalties

(1) Natural persons who deliberately commit offences may be liable to imprisonment up to [X] years and/or fines.

Alternative A — Salary-linked penalties

A responsible natural person may be fined up to [one/two/three] times annual net income.

Alternative B — Fixed and custodial ranges

Specified offences may be punished by fines up to [amount] or imprisonment up to [X] years.

Alternative C — Day-fine system

(1) Financial penalties shall be calculated by reference to the offender's daily income and offence seriousness.

(2) A legal person may be fined up to:
(a) [X] currency units;
(b) [2/5/10/20] percent of annual worldwide or domestic turnover; or
(c) [two/three] times the economic benefit,
whichever is higher.

(3) Sanctions shall be doubled for repetition.

(4) Imprisonment applies for:
(a) supply to minors;
(b) large-scale illicit manufacture or import;
(c) adulteration causing death or serious injury;
(d) organised crime involvement;
(e) obstruction of justice;
(f) falsification causing serious harm; and
(g) repeat serious offences.

(5) An infringement is aggravated where it involves:
(a) supply to children;
(b) organised illicit manufacture or import;
(c) products presenting serious health risks;
(d) false safety or therapeutic claims;
(e) intentional falsification of records;
(f) destruction of evidence;
(g) obstruction of enforcement;
(h) retaliation against whistleblowers;
(i) repeated infringement; or
(j) substantial illicit turnover.

35.3 Administrative fines

(1) The ACT Agency may impose administrative fines based on:
(a) a fixed amount;
(b) a percentage of annual turnover;
(c) a multiple of economic benefit; or
(d) a combination thereof.
(2) The ACT Agency may impose daily penalties of up to [X] per day for continuing non-compliance.
(3) The ACT Agency may apply multipliers for severity.
(4) The ACT Agency may provide a reduction for early payment.
(5) The ACT Agency may increase fines for obstruction.

35.4 Operational restrictions

The ACT Agency may:
(a) suspend or revoke licences;
(b) impose temporary or permanent activity bans;
(c) impose debarment from corporate positions;
(d) prohibit public tender participation;
(e) close premises;
(f) order winding up;
(g) order divestment;
(h) impose mandatory recall;

(i) restrict financial instruments;
(j) suspend stock trading;
(k) restrict executive compensation;
(l) restrict dividend payments;
(m) impose external administration;
(n) appoint independent monitors;
(o) restrict advertising;
(p) restrict market access;
(q) impose mandatory compliance programmes;
(r) require financial guarantees; and
(s) impose any other proportionate restriction.

35.5 Asset seizure and financial measures

The ACT Agency may:
(a) confiscate property related to offences;
(b) freeze assets;
(c) order disgorgement of profits;
(d) create escrow accounts;
(e) confiscate indirect gains;
(f) require deposit of security;
(g) restrict offshore structures;
(h) seize manufacturing equipment;
(i) seize raw materials;
(j) seize transport vehicles;
(k) seize financial records;
(l) seize digital assets;
(m) order restitution; and
(n) recover enforcement costs.

35.6 Transparency and reputational measures

The ACT Agency may:
(a) publish infringement decisions;
(b) maintain a public blacklist;
(c) require public disclosure;
(d) require corrective statements;
(e) require apologies;
(f) require consumer education;
(g) maintain enforcement registers;
(h) issue public warnings;
(i) publish league tables;
(j) require disclosure of beneficial ownership;
(k) require lobbying disclosure;

(l) require sustainability reporting;
(m) name and shame;
(n) issue compliance certificates; and
(o) withdraw compliance certificates.

35.7 Remediation and compensation

The ACT Agency may order:
(a) compensation to victims;
(b) victim compensation funds;
(c) rehabilitation programmes;
(d) remedial measures;
(e) improvement plans;
(f) research funding;
(g) community service;
(h) cooperation with investigations;
(i) environmental remediation;
(j) product destruction;
(k) recall costs;
(l) treatment costs; and
(m) any other appropriate remediation.

35.8 Deferred prosecution and alternatives

(1) Deferred prosecution agreements may be offered requiring:
(a) admission of facts;
(b) payment;
(c) remediation;
(d) cooperation;
(e) monitoring;
(f) compliance reforms;
(g) prosecution upon breach.
(2) Alternatives include:
(a) probation;
(b) suspended sentences;
(c) mandatory treatment;
(d) community service;
(e) education programmes;
(f) restorative justice; and
(g) conditional discharge.

35.9 Sanctions for specific infringements

The following sanctions for specific infringements apply
(a) Supply to minors: [from … to …];
(b) Advertising violations: [from … to …];

(c) Traceability violations: [from … to …];
(d) Product safety violations: [from … to …];
(e) Licensing violations: [from … to …];
(f) Tax evasion: [from … to …];
(g) Illicit trade of regulated products or prohibited products: [from … to …];
(h) Obstruction of investigation or enforcement: [from … to …];
(i) Falsification of documents or data relevant for this Regulation: [from … to …];
(j) Environmental violations: [from … to …];
(k) Data protection violations: [from … to …];
(l) Whistleblower or witness retaliation: [from … to …];
(m) Non-cooperation: [from … to …];
(n) Failure to report: [from … to …];
(o) Misleading claims: [from … to …]; and
(p) Circumvention of obligations: [from … to …].

35.10 Group and controlling-person liability

(1) Sanctions may extend to parent persons.
(2) Sanctions may extend to subsidiary, controlling persons, contractors, to their officers and to officers of parent persons who:
(a) directed or authorised the infringement;
(b) knowingly facilitated it;
(c) exercised decisive control;
(d) failed to prevent it despite a duty;
(e) received substantial benefit; or
(f) failed to report known infringements.

35.11 Automatic expiry of sanctioning procedures

Sanctioning procedures not concluded within [X] months expire automatically, unless extended for justified reasons.

35.12 Ne bis in idem

No person shall be sanctioned twice by different authorities for the same factual infringement.

Section 36 — Joint Liability and Compensation

36.1 Joint and several liability

Operators may be jointly and severally liable for damage caused by defective, unlawful, or materially misrepresented regulated products.

36.2 Liability categories

Liability extends to:
(a) manufacturers;
(b) importers;

(c) distributors;
(d) own-branders;
(e) authorised representatives;
(f) fulfilment service providers;
(g) online marketplaces [where they fail in due diligence];
(h) service providers;
(x) licensors; and
(j) the persons referred to in Subsection 35.10.

36.3 Damage categories

Liability covers:
(a) death;
(b) personal injury;
(c) poisoning;
(d) dependence-related harm;
(e) disease caused by consumption;
(f) injury to third parties from impairment;
(g) second-hand exposure harm;
(h) all damages caused by battery fire, explosion, or overheating;
(i) all poisoning and other chemical damage;
(j) environmental damage;
(k) loss of support;
(l) psychological harm;
(m) economic loss;
(n) property damage; and
(o) pure economic loss from reliance on misrepresentations.

36.4 Causation models

Alternative A — Ordinary proof

(1) The claimant must prove defect, damage and causation under general law.

Alternative B — Rebuttable presumption

(1) Causation is presumed where exposure and damage satisfy prescribed scientific criteria, unless the operator proves a more probable alternative cause.

Alternative C — Non-compliance presumption

(1) Causation is presumed where the product failed to comply with a safety, warning, child-resistance or content requirement materially related to the injury.
(2) Where the responsible producer cannot be identified, liability may be allocated among operators according to market share.

36.5 Device incidents

Where a device explodes, burns or overheats during normal use, defect is rebuttably presumed unless the operator proves compliance and manifest misuse.

36.6 Liability insurance

(1) Liability insurance is mandatory for:
(a) manufacturers;
(b) importers;
(c) high-risk product categories;
(d) consumption venues; and
(e) other operators prescribed by the ACT Agency.
(2) Direct rights against insurers may be provided.

36.7 Compensation fund

Alternative A — Complementary function

(1) A national compensation fund for victims who are unable to sue a precise operator may **OR** must be established by the ACT Agency.
(2) It must be financed by operator contributions.

Alternative B — Substituting function

(1) A national compensation fund for victims may **OR** must be established by the ACT Agency.
(2) It must be financed by operator contributions.
(3) Operators remain liable, but claims shall first be paid from the fund.
(4) Fund payment extinguishes operator liability to the extent of payment[, except for deliberate misconduct].

Section 37 — Legal Remedies and Dispute Resolution

37.1 Right to be heard

Before adverse decisions, affected persons must:
(a) be notified of the proposed action;
(b) be given reasons;
(c) have opportunity to respond;
(d) have access to relevant evidence;
(e) be able to present their case; and
(f) receive a reasoned decision.

37.2 Administrative review

(1) Internal administrative review is a precondition for the review by tribunals or courts.
(2) The internal review is presumed to be negative if no decision is taken within [30] days.
(3) [Rules on judicial review.]

37.3 Independent tribunal

(1) An independent specialised Regulatory Appeals Tribunal is hereby established.
(2) The Government must adopt rules on its setting-up, the nomination of its judges, its functioning, and its financial management.
(3) The Regulatory Appeals Tribunal may:
(a) affirm, vary, or set aside decisions;
(b) remit matters;
(c) substitute decisions;
(d) issue interim orders;
(e) award costs; and
(f) refer questions of law.

37.4 Third-party standing

(1) The following may seek enforcement, injunctive relief or compensation of damages, including compensation for public households:
(a) directly affected persons;
(b) consumer organisations;
(c) public health organisations;
(d) environmental organisations;
(e) local authorities;
(f) competitors;
(g) trade associations;
(h) the ombudsman; and
(i) any person with sufficient interest.
(2) The persons referred to in Paragraph (1) also have standing in any procedure referred to in this Regulation.

37.5 Alternative dispute resolution (ADR)

(1) The ACT Agency may prescribe ADR for certain disputes, but solely as a preliminary step to ordinary procedures.
(2) ADR does not replace enforcement.
(3) ADR must not be used to delay urgent protective action.

37.6 Class actions and collective redress

(1) Collective actions may be brought by:
(a) registered consumer organisations;
(b) public health organisations;
(c) groups of [X] or more affected persons; and
(d) the Ombudsman or the ACT Agency on behalf of consumers.
(2) The Government may prescribe opt-in or opt-out mechanisms.

37.7 Invalidity clauses

Rules, decisions, or contracts adopted in breach of this Regulation are void to the extent of the breach.

CHAPTER 8 — DATA, INFORMATION AND ARTIFICIAL INTELLIGENCE

Section 37A — Data Protection and Privacy

37A.1 Data minimisation

Only data strictly necessary for regulatory purposes may be collected.

37A.2 Purpose limitation

(1) Data collected for one purpose may not be used for another without legal basis.
(2) Consumption data must not be used for marketing.

37A.3 Storage limitation

Data must be deleted after the prescribed retention period.

37A.4 Security

Appropriate technical and organisational measures must protect data.

37A.5 Rights

Data subjects have rights of access, correction, deletion, and portability.

37A.6 Cross-border data transfers

Cross-border data transfers require adequate protection established by agreements.

Section 37B — Transparency of Algorithmic Systems

37B.1 General obligations

Operators using algorithmic systems for pricing, targeting, recommendation, or content moderation must:
(a) disclose the use of such systems;
(b) provide meaningful information about the logic;
(c) ensure human oversight;
(d) prevent discriminatory outcomes;
(e) maintain audit trails;
(f) conduct regular assessments; and
(g) provide explanation for significant decisions.

37B.2 Dark patterns

Dark patterns in digital interfaces for regulated products are prohibited.

37B.3 Right of human review

Everybody has the right to human review of automated decisions affecting access to regulated products or services.

Section 37C — Open Data and Public Access

37C.1 ACT Agency publication obligation

(1) The ACT Agency shall proactively publish:
(a) enforcement data;
(b) product registers;
(c) licence registers;
(d) inspection results;
(e) safety alerts;
(f) research findings;
(g) guidance documents;
(h) meeting minutes;
(i) consultation responses;
(j) performance indicators; and
(k) financial reports.
(2) Personal data and legitimate confidential information may be withheld.

37C.2 Publication formats

Data must be published in open, machine-readable formats.

CHAPTER 9 — EMERGENCIES AND CRISIS MANAGEMENT

Section 37D — Emergency Rules

37D.1 Powers

Where a serious and urgent threat to public health arises from regulated products, the Minister/Government/ACT Agency may:
(a) issue emergency orders restricting or prohibiting products;
(b) suspend regulatory requirements temporarily;
(c) authorise emergency use of alternative products;
(d) impose rationing or allocation;
(e) requisition production capacity;
(f) control prices;
(g) restrict exports;
(h) mandate production;

(i) suspend licences;
(j) close premises;
(k) impose curfews on sales;
(l) deploy emergency resources;
(m) issue public warnings;
(n) coordinate with international bodies;
(o) activate contingency plans;
(p) adopt temporary regulatory acts to adapt the legal framework to the emergency;
(q) issue temporary derogations; and
(r) take any other necessary measure.

37D.2 Limitations

Emergency measures must be:
(a) proportionate;
(b) time-limited;
(c) subject to parliamentary scrutiny;
(d) reviewed regularly;
(e) revoked when no longer necessary;
(f) published immediately; and
(g) accompanied by reasons.

Section 37E — Contingency Planning

37E.1 Cases covered by contingency plans

The ACT Agency must maintain contingency plans at least for:
(a) large scale product contamination events;
(b) supply chain disruption of products that are less harmful than their alternatives;
(c) massive illicit trade surges;
(d) fast spreading of novel harmful substances;
(e) massive device safety incidents;
(f) cyberattacks on regulatory systems; and
(g) mass poisoning events.

37E.2 Content of contingency plans

Contingency plans must include:
(a) risk assessment;
(b) trigger criteria;
(c) response procedures;
(d) communication protocols;
(e) resource allocation;
(f) coordination arrangements;
(g) recovery procedures;
(h) review and update cycles;

(i) exercise and testing schedules;
(j) cooperation with national institutions;
(k) international cooperation; and
(l) post-incident evaluation.

CHAPTER 10 — FINANCIAL IMPLEMENTATION AND GENERAL PLANNING

Section 37F — Multi-annual Planning

37F.1 Content of multi-annual plans

The ACT Agency must prepare multi-annual strategic plans covering:
(a) objectives and targets;
(b) resource requirements;
(c) enforcement priorities;
(d) research agenda;
(e) cooperation with national institutions;
(f) international cooperation;
(g) capacity building;
(h) performance indicators;
(i) risk assessment;
(j) stakeholder engagement; and
(k) review mechanisms.

37F.2 Annual operation plans

The ACT Agency must prepare annual operational plans covering:
(select from previous list)

37F.3 Publication

Plans must be published at the latest in March of each year.

Section 37G — Procurement

37G.1 Joint procurement

The ACT Agency may participate in joint procurement of:
(a) testing equipment;
(b) laboratory services;
(c) IT systems;
(d) training services;
(e) research services;
(f) enforcement equipment; and
(g) other prescribed goods and services.

37G.2 — Procurement integrating compliance

(1) Public procurement of products and services must verify regulatory compliance.
(2) Public procurement may prefer products and services exceeding minimum standards.
(3) Public procurement may exclude non-compliant operators even where the non-compliance relates to another regulation.

CHAPTER 11 — FINAL PROVISIONS

Section 38 — Entry into Force and Application Dates

38.1 Entry into force

This Regulation enters into force on [date].

38.2 Staged application

(1) Institutional and rulemaking provisions shall apply immediately.
(2) Obligations regarding the notification or registration of products and operators shall apply as from [X] months.
(3) Obligations regarding licensing apply as from [Y] months. However, licensing procedures are open as from [X] months.
(4) Packaging and warning requirements or obligations apply as from [Y] months.
(5) Product reformulation requirements and product standards apply as from [Z] months.
(6) Traceability requirements and obligations apply as from [Z] months.
(7) Environmental recovery schemes and related requirements or obligations apply as from [Z] months.
(8) Prohibitions on specified products, substances or components apply on the prescribed date and, where established by this Regulation, as from [Y] months.
(9) All other rules set out in this Regulation apply as from [Y] months.

38.3 Preconditions

An obligation dependent on ACT Agency training, registration or infrastructure must not become enforceable before that system is reasonably operational, except where urgent health protection requires otherwise.

Section 39 — Transitional Provisions

39.1 Existing operator licences

Alternative A — Grandfathering

Operator licences issued under [predecessor legislation] remain valid until their stated expiry.

Alternative B — Renewal

Existing operators must obtain a new licence within [X] months.

39.2 Existing operators

An operator active on the date of publication must, pending the outcome of its licensing procedure:
(a) fulfil its notification and registration obligations;
(b) maintain at least its current safety level; and
(c) not introduce new products without registration or licensing, subject to the case.

39.3 Existing products

Products lawfully placed on the market by a manufacturer or importer before commencement may continue to be sold until:
(a) stocks are exhausted;
(b) [Z] months have elapsed; or
(c) a serious-risk order takes effect, whichever occurs first.

39.4 Packaging stock

Existing packaging may be used for up to [Y] months unless it:
(a) lacks an essential health warning;
(b) is materially misleading;
(c) appeals predominantly to children; or
(d) relates to a prohibited product.

39.5 Product authorisation transition

A previously authorised, but newly regulated product may remain on the market for [Y] months after the license commencement if:
(a) the manufacturer or importer submits a complete notification within [30/90] days;
(b) no serious risk is identified;
(c) interim warnings are applied; and
(d) prescribed reporting obligations are fulfilled.

39.6 Geographic monopolies

Existing geographic monopolies remain valid until [date] or must be reallocated under Section 9 within [X] months.

39.7 Long-shelf-life products

The ACT Agency may prescribe special transitional periods for products with shelf lives exceeding [Z] months, provided that public health is not materially compromised.

39.8 Shortening or extension

(1) The ACT Agency may:
(a) shorten a transitional period for a product presenting a serious risk; or
(b) extend a period where necessary to prevent disproportionate disruption without materially compromising health.
(2) Reasons must be published.

39.9 Further transitional provisions

Existing sponsorship agreements, cultivation operations, and existing consumption venues remain legal and valid for [Y] months.

Section 40 — Review

40.1 Periodicity

This Regulation shall be reviewed every [5] years.

40.2 Content

The review shall assess:

(a) effectiveness against objectives;

(b) proportionality;

(c) distributional effects;

(d) unintended consequences;

(e) enforcement adequacy;

(f) regulatory gaps;

(g) international alignment;

(h) cost-effectiveness;

(i) technological developments;

(j) market developments;

(k) scientific evidence; and

(l) stakeholder views.

Section 41 — Remedies Against Overregulation

41.1 Petitions

Operators may petition for review where cumulative or conflicting requirements create disproportionate burden.

41.2 Regulatory overlap

The ACT Agency must maintain a mechanism for identifying and resolving regulatory overlap.

41.3 Binding interpretation in case of conflict

Operators may request binding interpretation where requirements conflict.

Section 42 — Relationship with Other Laws

42.1 Supplementary role

This Regulation supplements and does not replace:

(a) criminal law;

(b) consumer protection law;

(c) competition law;

(d) environmental law;
(e) data protection law;
(f) tax law;
(g) customs law;
(h) occupational health and safety law;
(i) industry products law;
(j) food safety law;
(k) advertising law;
(l) intellectual property law;
(m) contract law;
(n) tort law; and
(o) other applicable law.

42.2 Collision rules

Where this Regulation conflicts with another law, [this Regulation prevails / the more protective provision prevails / specific conflict rules apply / the more recent rule prevails].

46.3 No compliance substitution

Compliance with this Regulation does not exempt from compliance with other applicable law.

Section 43 — Electronic Proceedings

43.1 Voluntary electronic submissions

All applications, notifications, and communications under this Regulation may be submitted electronically.

43.2 Mandatory electronic submissions

The ACT Agency may mandate electronic submission for specified procedures.

43.3 Electronic signatures

Electronic signatures conforming to standard … are valid.

43.4 Electronic documents

Electronic documents have the same legal effect as paper documents.

Section 44 — Confidentiality

44.1 Principle

Information obtained under this Regulation must be treated confidentially except where disclosure is:
(a) required by law;
(b) necessary for enforcement;
(c) in the public interest;
(d) consented to by the provider;

(e) necessary for protection of health;
(f) required by court order; or
(g) necessary for international cooperation.

44.2 Commercial confidential information
Commercial confidential information must be protected.

44.3 Personal data
Personal data must be protected in accordance with data protection law.

44.4 Whistleblower identity
The identities of whistleblowers must be protected even where other rules call for their disclosure.

Section 45 — Implementing regulations

45.1 Principle
The [Government / ACT Agency] may adopt regulations to implement this Regulation.

45.2 Content
Regulations may:
(a) prescribe technical standards;
(b) set limits and thresholds;
(c) establish procedures;
(d) create forms and templates;
(e) set fees;
(f) designate products;
(g) establish exemptions;
(h) create transition arrangements;
(i) update annexes;
(j) establish testing methods;
(k) prescribe training requirements;
(l) set reporting formats;
(m) establish registers;
(n) create enforcement procedures;
(o) set penalty amounts;
(p) make any other provision necessary for implementation; and
(q) adapt this Regulation to technical progress.

45.3 Formalities
(1) Regulations must be:
(a) published;
(b) subject to public consultation;
[(c) subject to impact assessment;] (not recommended)

(d) subject to parliamentary scrutiny; and
(e) reviewed periodically.
(2) Emergency regulations may be adopted without prior public consultation [and without impact assessment].

Section 46 — Publication Modalities

46.1 Table of contents
The publication of this Regulation must include a table of contents.

46.2 Explanatory notes
Explanatory notes may accompany each section.

46.3 Hyperlinks
Hyperlinks to related provisions may be included in electronic versions.

46.4 Pop-up definitions
Pop-up definitions may be included in electronic versions [for terms defined in this Regulation] **OR** [even where a term has not been defined in this Regulation].

Section 47 — Annexes
(Detailed annexes to be developed, including:)
The following Annexes form part of this Regulation. To the extent they are not set out here, the [Government / ACT Agency] may adopt or complement them in accordance with Section 45:

Annex I — Designated Substances
[List of artificial cannabinoids, synthetic nicotine, novel psychoactive substances, with update mechanism]

Annex II — Traditional Psychoactive Products
[Coca, khat, betel nut, kava, ayahuasca, peyote, etc., with specific rules]

Annex III — Psychoactive Fungi
[Psilocybin mushrooms, etc.]

Annex IV — Prohibited Goods
[Complete list with descriptions]

Annex V — Prohibited and Restricted Additives
[Positive and negative lists with conditions]

Annex VI — Product-Specific Requirements
[Detailed requirements for each product category]

Annex VII — Warning Texts and Images
[Rotating warning sets for each product category]

Annex VIII — Testing Methods
[Prescribed testing protocols and standards]

Annex IX — Traceability Requirements
[Detailed traceability specifications]

Annex X — Licence Categories and Conditions
[Detailed conditions for each licence type]

Annex XI — Fee Schedules
[Detailed fee structures]

Annex XII — Penalty Schedules
[Detailed penalty amounts and criteria]

Annex XIII — Transitional Provisions
[Detailed transition arrangements for operators' licences and registration or licensing of products, prescribing for how long licences issued under the previous law remain valid and for how long products covered by the old licences or simply conforming to the previous law may (a) be produced or imported, (b) enter the national distribution chain and (c) be sold to consumers. See also Section 81 of our Cross-sectoral Standard Provisions]

Annex XIV — Correlation Table
[Mapping to previous legislation]

Annex XV — Forms and Templates
[All prescribed forms]

Annex XVI — Consumer Units
[Prescribed quantities for each product]

Annex XVII — Prohibition Zones
[Detailed geographic restrictions]

Annex XVIII — Warning Rotation Schedule
[Timeline for warning changes]

Annex XIX — Reporting Formats
[Standardised reporting templates]

Annex XX — Risk Classification Criteria
[Methodology for risk assessment]

CANDIDATE ADD-ON ELEMENTS

In the following, we list add-on elements that might be regarded as going too far by most readers. However, we recommend verifying each element, and namely those of Sections I to L.

A. Regulatory Impact Assessment

(not recommended, structurally not feasible to evaluate comparatively different scenarios where there are dozens of content parameters from which drafters can choose)
Before adopting any regulation under this Act, the ACT Agency shall conduct a regulatory impact assessment examining: (a) the problem and objectives; (b) policy options including non-regulatory options; (c) costs and benefits; (d) impacts on small businesses; (e) distributional effects; (f) environmental effects; (g) international implications; (h) enforcement feasibility; (ix) consultation summary; and (j) monitoring and review arrangements.

B. Stakeholder Consultation

(1) Before adopting regulations, the ACT Agency shall consult: (a) public health organisations; (b) industry associations; (c) consumer groups; (d) academic experts; (e) local authorities; (f) enforcement agencies; (g) international bodies; (h) affected communities; (ix) youth representatives; (j) environmental organisations; and (k) the general public. (2) Consultation must be: (a) timely; (b) accessible; (c) transparent; (d) documented; (e) responded to; and (f) published.

C. Whole-Society Consultation — Optional

For major regulatory changes, a whole-society consultation mechanism may be established involving: (a) citizens' assemblies; (b) public hearings; (c) online consultations; (d) community engagement; (e) youth panels; (f) expert roundtables; (g) industry forums; (h) civil society dialogues; (ix) parliamentary committee hearings; and (j) media engagement.

D. Stakeholder Forum

A permanent Stakeholder Forum may be established to: (a) provide ongoing input; (b) review implementation; (c) identify emerging issues; (d) facilitate dialogue; (e) review guidance; (f) propose improvements; and (g) monitor industry conduct.

E. Joint Programming and Co-Regulatory Roadmapping

(1) The ACT Agency may engage in joint programming with stakeholders for: (a) long-term regulatory strategy; (b) technology transitions; (c) phase-out plans; (d) innovation pathways; (e) harm reduction roadmaps; (f) environmental transition plans; and (g) international alignment schedules.

F. Binding Sectoral Roadmaps

(1) The ACT Agency may establish binding roadmaps with: (a) clear milestones; (b) reporting requirements; (c) enforcement mechanisms; (d) review points; (e) stakeholder commitments; (f) penalty provisions; and (g) public publication.

G. Voluntary Agreements

(1) The ACT Agency may recognise voluntary agreements as compliance tools where: (a) they meet prescribed standards; (b) they are monitored; (c) they include enforcement mechanisms; (d) they have fall-back regulatory solutions; (e) they are time-limited; (f) they are reviewed; and (g) they do not substitute for necessary regulation.

H. Regulatory Sandboxes and Experimentation

(1) The ACT Agency may authorise time-limited controlled trials of: (a) regulatory measures; (b) service models; (c) harm-reduction interventions; (d) new products; (e) enforcement approaches; (f) technology applications; (g) business models; and (h) compliance mechanisms. (2) Authorisations must specify: (a) scope and duration; (b) conditions and safeguards; (c) data collection; (d) independent evaluation; (e) termination criteria; (f) consumer protection; (g) non-derogable requirements; and (h) publication of results. (3) Trials must not waive: (a) minimum-age requirements; (b) prohibitions on involuntary exposure; (c) data protection requirements; (d) prohibitions on misleading claims; (e) safety requirements; or (f) other prescribed safeguards.

I. Public Education and Awareness — Comprehensive Package

(1) The ACT Agency shall develop and implement public education campaigns: (a) targeting different populations; (b) addressing all product categories; (c) providing cessation information; (d) countering misinformation; (e) based on scientific evidence; (f) evaluated for effectiveness; (g) culturally appropriate; (h) accessible to persons with disabilities; (ix) in multiple languages; and (j) using multiple channels. (2) The ACT Agency shall establish: (a) a national helpline; (b) an online resource centre; (c) a reporting mechanism; (d) educational materials for schools; (e) training for health professionals; (f) public awareness events; and (g) social media presence.

J. Protection of Minors — Comprehensive Package

(1) All provisions of this Regulation must be applied with particular regard to protection of minors. (2) Additional protections include: (a) prohibition of sales to minors; (b) prohibition of proxy purchases; (c) prohibition of free distribution to minors; (d) prohibition of advertising directed at minors; (e) prohibition of packaging appealing to minors; (f) prohibition of flavours appealing to minors; (g) prohibition of placement near schools; (h) prohibition of vending machines accessible to minors; (ix) prohibition of online sales without age verification; (j) prohibition of sponsorship of youth events; (k) prohibition of product placement in youth media; (l) mandatory age verification for all sales; (m) education programmes in schools; (n) support services for minors; (o) prohibition of criminal penalties for minor possession; (p) diversion programmes; (q) family support; (r)

protection from exploitation; (s) data protection for minors; (t) prohibition of algorithmic targeting of minors; (u) prohibition of gamification targeting minors; (v) prohibition of social media marketing to minors; (w) prohibition of influencer marketing reaching minors; (x) prohibition of loyalty schemes for minors; (y) prohibition of subscription services for minors; and (z) any other prescribed protection.

K. Environmental Protection

(1) Operators must minimise environmental impact across the product lifecycle. (2) Specific obligations include: (a) extended producer responsibility; (b) collection and recycling schemes; (c) prohibition of unnecessary packaging; (d) biodegradability requirements where feasible; (e) prohibition of single-use products where alternatives exist; (f) battery recovery obligations; (g) chemical waste management; (h) water protection; (ix) air emission limits; (j) soil contamination prevention; (k) biodiversity protection; (l) carbon footprint reporting; (m) environmental impact assessment for cultivation; (n) sustainable sourcing requirements; (o) waste reduction targets; (p) recycling content requirements; (q) disposal information; (r) take-back obligations; (s) environmental levies; (t) green public procurement; and (u) environmental monitoring.

L. Health Inequalities

(1) The ACT Agency must monitor and address health inequalities in: (a) access to cessation services; (b) exposure to marketing; (c) availability of products; (d) enforcement patterns; (e) health outcomes; (f) economic burden; (g) environmental exposure; (h) data collection; (ix) research participation; and (j) policy development. (2) Targeted interventions may be prescribed for disproportionately affected communities. (3) Enforcement must not discriminate against vulnerable populations.

M. Proportionality for Small Operators

(1) Regulatory requirements must be proportionate to operator size. (2) Micro-enterprises may benefit from: (a) simplified registration; (b) reduced reporting; (c) extended transition periods; (d) fee reductions or exemptions; (e) simplified compliance procedures; (f) group compliance mechanisms; (g) shared services; (h) technical assistance; (ix) reduced inspection frequency; and (j) graduated enforcement. (3) De minimis exemptions may apply below prescribed thresholds.

N. Non-Discrimination and Equal Access

(1) Regulatory measures must not discriminate on grounds of: (a) nationality; (b) place of establishment; (c) size; (d) ownership; (e) product origin; (f) distribution channel; or (g) other irrelevant criteria. (2) Measures must be justified by legitimate public health objectives.

O. Freedom of Information and Transparency

(1) All regulatory decisions must be reasoned. (2) Registers must be publicly accessible. (3) Enforcement data must be published. (4) Guidance must be published. (5) Consultation responses must be published. (6) Meeting minutes must be published. (7) Financial reports must be published. (8) Performance data must be published.

P. Continuity of Proceedings

(1) Legislative changes do not affect: (a) pending proceedings; (b) existing liabilities; (c) acquired rights; (d) ongoing investigations; (e) existing licences (until expiry); (f) existing registrations; (g) existing authorisations; (h) enforcement actions in progress; (ix) appeal proceedings; (j) compensation claims; and (k) criminal proceedings. (2) Transitional provisions must address each category.

Q. Regulatory Correction Following Court Rulings

(1) Where a court declares a provision invalid or interprets it restrictively, the ACT Agency shall: (a) assess the impact; (b) issue guidance; (c) propose legislative amendment; (d) adjust enforcement practice; (e) notify affected operators; (f) update registers; and (g) publish the correction.

R. Mandatory Electronic Proceedings — Detailed

(1) Electronic submission is permitted for all procedures. (2) The ACT Agency may mandate electronic submission for specified categories. (3) Electronic signatures conforming to [applicable standard] are valid. (4) Electronic documents have the same legal effect as paper. (5) The ACT Agency must maintain secure electronic systems. (6) Accessibility requirements apply to all electronic systems. (7) Backup and recovery procedures must be in place. (8) Cybersecurity measures must be implemented.

S. Model Forms and Templates

(1) The ACT Agency shall prescribe model forms for: (a) licence applications; (b) product registration; (c) notifications; (d) reports; (e) complaints; (f) appeals; (g) declarations; (h) certificates; (ix) warnings; (j) enforcement notices; (k) recall notices; (l) inspection reports; (m) incident reports; (n) traceability records; (o) training records; (p) compliance declarations; (q) conformity assessments; (r) adverse event reports; (s) cessation records; (t) environmental reports; and (u) any other prescribed form. (2) Forms must be: (a) accessible; (b) available electronically; (c) in official languages; (d) clearly structured; (e) accompanied by guidance; (f) regularly updated; and (g) machine-readable where appropriate.

T. Capping of Compliance Costs

(1) The ACT Agency may cap fees and charges to ensure accessibility. (2) Fee structures must be transparent. (3) Fee waivers may be available for small operators. (4) Cost recovery must be proportionate.

U. Sanction Waiver for Information

(1) Sanctions may be waived or reduced for persons providing information on infringements. (2) Conditions include: (a) information is new and material; (b) disclosure is voluntary; (c) cooperation is full; (d) no coercion of others; (e) information leads to enforcement; (f) proportionality is maintained; and (g) public interest is served.

V. Incentives for Over-Compliance

(1) The ACT Agency may provide incentives for: (a) voluntary over-compliance; (b) innovation in harm reduction; (c) environmental excellence; (d) cessation support; (e) research participation; (f) whistleblowing; (g) early compliance; (h) best practice sharing; (ix) community engagement; and (j) international cooperation. (2) Incentives may include: (a) reduced inspection frequency; (b) simplified procedures; (c) fee reductions; (d) public recognition; (e) priority processing; (f) extended licence validity; (g) reduced reporting; (h) certification of excellence; (ix) tax benefits; and (j) grant eligibility.

W. Benchmarking and League Tables

(1) The ACT Agency may publish comparative performance data for: (a) operators; (b) product categories; (c) geographic areas; (d) enforcement authorities; (e) compliance rates; (f) harm indicators; (g) cessation rates; (h) illicit trade levels; (ix) environmental performance; and (j) customer satisfaction.

X. Social Partners in Regulatory Committees

(1) Regulatory committees may include representatives of: (a) workers; (b) employers; (c) consumers; (d) public health; (e) environment; (f) youth; (g) communities; (h) academia; (ix) enforcement; and (j) other prescribed stakeholders.

Y. Good Administrative Practice

(1) All authorities must comply with good administrative practice including: (a) legality; (b) proportionality; (c) legal certainty; (d) legitimate expectations; (e) right to be heard; (f) reasoned decisions; (g) access to files; (h) reasonable timeframes; (ix) non-discrimination; (j) transparency; (k) accountability; (l) efficiency; (m) courtesy; (n) accessibility; (o) data protection; (p) confidentiality; (q) impartiality; (r) independence; (s) diligence; (t) consistency; and (u) continuous improvement.

Z. Protection Against Conflicting Instructions

(1) Where an operator receives conflicting instructions from different authorities, the operator may request a coordinated response. (2) A lead authority may be designated. (3) The ACT Agency may issue binding coordination decisions.

PRINCIPAL SOURCES OF INSPIRATION

This document integrates, according to the AI used for its elaboration, material from:

- **Regulatory Institute / howtoregulate.org:** - Model Law on Alcohol, Cannabis and Tobacco Prevention - EU Legislators' Toolbox (387 entries) - Commonwealth and Latin American Legislators' Toolbox (339 entries) - Cross-sectoral Standard Provisions - List of Powers and Obligations - List of Sanctions and Collateral Measures - Handbook "How to Regulate?" - EU Products Act Candidate Components
- **International instruments:** - WHO Framework Convention on Tobacco Control (2003) - WHO Protocol to Eliminate Illicit Trade in Tobacco Products (2012) - WHO FCTC Article 5.3 Guidelines - WHO FCTC Articles 8-15 Guidelines - WHO Framework for alcohol control - UN Sustainable Development Goals - International Covenant on Economic, Social and Cultural Rights - Convention on the Rights of the Child
- **EU legislation:** - Tobacco Products Directive 2014/40/EU - Tobacco Advertising Directive 2003/33/EC - General Product Safety Regulation 2023/988 - Digital Services Act 2022/2065 - Batteries Regulation 2023/1542 - GDPR 2016/679 - AI Act 2024/1689 - Market Surveillance Regulation 2019/1020 - Regulation 2024/3110 (Construction Products) - Regulation 2017/745 (Medical Devices) - Regulation 2023/1114 (Crypto Assets) - Regulation 2025/40 (Packaging) - Regulation 2024/1781 (Ecodesign)
- **National legislation (selection):** - UK Tobacco and Vapes Act 2026 - UK Tobacco and Related Products Regulations 2016 - Australia Therapeutic Goods Act 1989 - Australia Tobacco Act 1982 - New Zealand Smokefree Environments and Regulated Products Act 1990 - Canada Tobacco and Vaping Products Act - US Federal Food, Drug, and Cosmetic Act - Finland Tobacco Act 549/2016 - Norway Tobacco Control Act - Sweden Act on Tobacco-Free Nicotine Products - France Loi n° 2025-175 (disposable vapes) - Belgium vaping regulations - Netherlands flavour restrictions - Germany Tobacco Tax Modernisation Act - Brazil Lei 9.782/1999 (ANVISA) - Colombia Ley 1335/2009 - Chile Ley 20.660 - Argentina Ley 26.687 - Mexico Ley General de Salud - Peru Ley 29571 - India Cigarettes and Other Tobacco Products Act 2003 - Singapore Tobacco (Control of Advertisements and Sale) Act - Kenya Public Health (Shisha Prohibition) Rules 2026 - South Africa Tobacco Products Control Act - Nigeria Federal Competition and Consumer Protection Act 2018 - UAE Federal Law No. 15/2009 - Saudi Arabia Tobacco Control Regulations - Japan Tobacco Business Act - South Korea National Health Promotion Act - Thailand Tobacco Products Control Act 2017 - Malaysia Control of Tobacco Products Act 2023 - Indonesia Government Regulation on Tobacco - Philippines Republic Act 9211 - Vietnam Law on Prevention of Harmful Effects of Tobacco - Bangladesh Smoking and Tobacco Products Usage Control Act - Sri Lanka National Authority on Tobacco and Alcohol Act - Pakistan Prohibition of Smoking and Protection of Non-Smokers Health Ordinance - Nepal Tobacco Products Control and Regulatory Act - Bhutan Tobacco Control Act 2010 - Ethiopia Tobacco Control Directive - Tanzania Tobacco Control Regulations - Uganda Tobacco Control Act 2015 - Rwanda Law on Tobacco Control - Mauritius Environment Act 2024 - Fiji Public Health Act - Papua New Guinea Tobacco Control Act - Solomon Islands Tobacco Control Act - Samoa Tobacco Control Act - Tonga

Tobacco Control Act - Lesotho Labour Act 2024 - Eswatini Suppression of Terrorism Act 2008 - Zimbabwe Tobacco Industry and Trade Act - Zambia Agricultural Credits and Warehouse Receipts Act 2026 - Malawi Competition and Fair Trading Regulations 2026 - Namibia Vehicle Mass Act 2024 - Botswana Tobacco Control Act - Ghana Public Health Act 2012 - Sierra Leone Prohibition of Child Marriage Act 2024 - Liberia Fisheries and Aquaculture Management Law 2019 - Belize Electricity Licensing Regulations 2024 - Guyana Planning and Development Single Window System Act 2023 - Paraguay Ley 6390 (Noise) - Uruguay Ley 19.568 - Ecuador Ley Orgánica de Simplificación Tributaria - Honduras Ley de Reactivación Económica 2026 - El Salvador Decreto 234 (AI) - Bolivia Ley 602 (Risk Management) - Cuba Decreto-Ley 102/2025 (Nuclear) - Dominican Republic Ley 41-23 - Costa Rica Reglamento 44741 (Chemical Accidents) - Nicaragua Decreto 09-2022 (Ozone) - Panamá Ley 430/2024 (Food Safety) - Guatemala Decreto 25-2024 (Vaccination) - MERCOSUR agreements - CARICOM agreements - African Union frameworks - ASEAN frameworks

- **Standards and technical documents:** - ISO 8317 (Child-resistant packaging) - ISO 20768 (Vaping emissions) - IEC 62133 (Battery safety) - ISO/IEC 17025 (Testing laboratories) - ISO/IEC 17065 (Product certification) - WHO TobReg recommendations - WHO technical reports on tobacco and nicotine - Codex Alimentarius standards - UNECE vehicle regulations - OECD test guidelines

This document is a working document intended for legislative development. All provisions require adaptation to the specific legal, constitutional, and administrative context of the adopting jurisdiction.