Unofficial Translation

No. 45479 -S

THE PRESIDENT OF THE REPUBLIC AND THE MINISTER OF HEALTH,

Based on Articles 50, 140, paragraphs 3) and 18), and 146 of the Constitution; 25, paragraph 1), 27, paragraph 1, 28, paragraph 2), subparagraph b) of Law No. 6227 of May 2, 1978, "General Law on Public Administration"; 1, 2, 4, 7, 130, 239, 240, 241, 242, 252, 345, paragraph 7), 359, 362, 363, 355, and 256 of Law No. 5395 of October 30, 1973 "General Health Law"; 39, 49, and 60 of Law No. 10473 of April 24, 2024, "National Quality System"; 1, 2, subsections b) and c), 6, and 56 bis of Law No. 5412 of November 8, 1973 "Organic Law of the Ministry of Health" and 1 and Annex B of Law No. 7475 of December 20, 1994, "Law Approving the Final Act Incorporating the Results of the Uruguay Round of Multilateral Trade Negotiations."

CONSIDERING:

1.- That the health of the population is a public interest protected by the State.

2.- That according to the article "Vaping poisonings double in the country and affect more minors" ("Intoxicaciones por vapeo se duplican en el país y afectan a más menores") published by La Nación on February 10, 2024, according to data from the National Poison Control Center (CNCI for its acronym in Spanish) of the Costa Rican Social Security Fund, in 2023, fourteen people suffered poisoning from vaping. Nine of those cases involved minors. Seven of the 14 cases required medical attention in hospitals due to symptoms such as: difficulty breathing, tachycardia, paleness, tremors, red eyes, coughing, nausea, and vomiting; as well as sweating, dizziness, low blood pressure, anxiety, and even hallucinations. The people who reported vaping poisoning were unaware of the substances contained in the vaporizer.

3.- That the results of the "VI National Survey on Psychoactive Substance Use in the Secondary School Student Population, Costa Rica 2021" ("VI Encuesta Nacional sobre Consumo de sustancias Psicoactiva en Población de Estudiantes de Educación Secundaria, Costa Rica 2021") published by the Institute on Alcoholism and Drug Dependence in a statement on November 20, 2023, on its website, determined that 131 students out of every thousand reported having vaped at some point; which means that high school students tripled their exposure to electronic devices, "(...) since in the survey conducted in 2018, the figure obtained was 46 per thousand." According to the Institute on Alcoholism and Drug Dependence (IAFA, in Spanish), "there is a group of minors who are exposed to the harmful effects of vaping. The aerosol from electronic cigarettes may contain nicotine and other addictive substances that cause cancer, lung disease, and heart disease. This is without taking into account that the combustion process that occurs during vaping is always, always harmful," and "When vaping contains nicotine or cannabis-derived substances, this behavior may slow brain development in adolescents, affecting memory, concentration, learning, self-control, attention, and mood..."

4.- That according to point 7 of the WHO Report FCTC/COP/7/11. Electronic nicotine delivery systems and similar nicotine-free systems, during the Seventh Meeting of the Conference of the

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Parties to the WHO Framework Convention on Tobacco Control, held in Delhi (India) from November 7 to 12, 2016, the typical use of unadulterated Electronic Nicotine Delivery Systems and Similar Non-Nicotine Delivery Systems produces an aerosol that typically contains glycols, aldehydes, volatile organic compounds (VOCs), polycyclic aromatic hydrocarbons, tobacco-specific nitrosamines (TSNAs), metals, silicate particles, and other components. Dicarbonyls (glyoxal, methylglyoxal, diacetyl) and hydroxycarbonyl (acetol) are also considered important components of the aerosol. Many of these components are toxic substances with known health effects that induce a variety of significant pathological changes.

5.- That the Costa Rican Social Security Fund (CCSS, for its acronym in Spanish) reported in November 2023 the first confirmed case of e-cigarette, or vaping, product use-associated lung injury (EVALI) in Costa Rica, in a person under the age of 16, according to an article published by Semanario Universidad in its digital edition on November 8, 2023. The syndrome generally presents with "difficulty breathing, cough, chest pain, rapid breathing (tachypnea), bloody phlegm, tachycardia, fever, feeling cold or fatigued, and/or gastrointestinal symptoms such as nausea, vomiting, diarrhea, and abdominal pain." This situation is of great concern to public health and requires immediate intervention in order to discourage consumption among minors.

6.- That the second Global Adult Tobacco Survey, 2022 (GATS), according to the statement published on the website of the Institute on Alcoholism and Drug Dependence on November 9, 2023, determined that in Costa Rica, despite efforts to reduce the use of tobacco products "(...) there has been an increase in the percentage of people who have ever used electronic cigarettes, from 4.1% in 2015 to 6.5% in 2022 (...) the percentage of people who have heard of electronic cigarettes increased from 47.5% in 2015 to 58.4% in 2022."

7.- That according to the "Declaration of Iberian-Latin American Pulmonary Scientific Societies on Electronic Nicotine Delivery Devices," published in May 2019, point 6. indicates that analysis of various studies shows that electronic nicotine delivery devices allow the inhalation of other flavoring substances, which, in addition to their addictive power, add new potential toxicities that can adversely affect the respiratory system.

8.- That according to the "Global Strategy for Nicotine Reduction, in the article Potential Health Effects of Electronic Cigarettes: A Systematic Review of Case Reports," in 2006, the short- or medium-term addiction caused by nicotine-based products intended for consumption by inhalation has been widely demonstrated.

9.- According to the New England Journal of Medicine, July 14, 1994, in the article "Establishing a Nicotine Threshold for Addiction: Implications for Tobacco Regulation," the maximum nicotine concentration allowed for liquids used for ENDS has been set at 20 mg/mL. This is because a higher content could contribute to an increased risk of developing dependence in young consumers, given that the value has been established in accordance with the average blood nicotine content of an active smoker of conventional tobacco-based cigarettes. It cannot be ruled out that the product may be harmful at concentrations of 20 mg/mL or lower.

10.- That, according to the "Report from the Commission to the European Parliament and the Council on the potential public health risks associated with the use of refillable electronic cigarettes," prepared in Brussels on May 20, 2016, by the European Commission, the consideration of a maximum permitted nicotine level will help reduce the risk for new consumers in the future, as well as prevent the risk of poisoning through accidental or deliberate ingestion or direct skin exposure.

11.- That, taking into account that, according to the Conference of the Parties to the WHO Framework Convention on Tobacco Control, at its Seventh Meeting held from November 7 to 12, 2016, in Delhi, India, many of the liquids used in Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems are toxic substances with known health effects that induce a variety of significant pathological changes; the Ministry of Health has determined the need to regulate such vaping liquids to reduce the risk of use of these products by the population.

12.- That, based on the article "Reducing the attractiveness of e-liquid to youth: a proposal for a restrictive list of tobacco-related flavoring ingredients" by the National Institute of Public Health and the Environment, obtained from the RIVM (Netherlands Institute for Public Health and the Environment, according to its Dutch acronym), it has been shown that banning certain flavoring ingredients in vaping liquids for public consumption has led to a reduction of up to 20% in consumption among young people and adults.

13.- That in recent years, the Ministry of Health has identified the marketing of chemical or natural substances or mixtures thereof, the consumption of which requires regulation by the Ministry, due to the fact that they pose an intrinsic risk of causing harm to human health, the severity of which depends on the quantity, frequency, and form of consumption. Therefore, the Ministry of Health has determined that it is necessary to regulate liquids used in electronic vaping devices as part of a category of products called "health risk products."

14.- That in accordance with Article 56 bis of Law No. 5412 of November 8, 1973, Organic Law of the Ministry of Health, individuals or legal entities, private or public, requiring permits or authorizations from the Ministry of Health relating to the control of physical, chemical, biological, and social factors affecting the human environment shall contribute financially to the payment of the service, in accordance with the rules issued by that Ministry and with the limitations established in the Financial Administration Law of the Republic.

15.- That, as indicated in Article 56 bis mentioned in the previous paragraph, the collection of fees for the procedures for administrative notification of raw materials and for administrative notification, renewing, and making changes after administrative notification of nicotine-containing or nicotine-free vaping liquids is appropriate insofar as it regulates an activity that affects the human environment. In this regard, the Acting Director of Radiological Protection and Environmental Health, in relation to the deficient technical management of vaping liquids present in electronic nicotine delivery systems and electronic non-nicotine systems, from their administrative notification to the treatment and final disposal of such liquids, and related

equipment and packaging materials, affects the environment, stated in official letter No. MS-DPRSA-1199-2024:

> *"1. According to point 7 of the WHO Report FCTC/COP/7/11. Electronic nicotine delivery systems and electronic non-nicotine delivery systems during the Seventh Session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, held in Delhi, India, from November 7 to 12, 2016, the typical use of unadulterated Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems produces an aerosol that typically contains glycols, aldehydes, volatile organic compounds (VOCs), polycyclic aromatic hydrocarbons, tobacco-specific nitrosamines (TSNAs), metals, silicate particles, and other components. Dicarbonyls (glyoxal, methylglyoxal, diacetyl) and hydroxycarbonyl (acetol) are also considered important components of the aerosol. Many of these components are toxic substances with known health effects that induce a variety of significant pathological changes, mediated by their environmental dissemination, in addition to their direct inhalation by the user.*
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> *2. The VOCs emitted by these systems can have synergistic effects with NOx and other compounds in the atmosphere, facilitating their transformation by sunlight and potentially generating photochemical smog, a respiratory irritant and environmental pollutant. https://www.sciencedirect.com/science/article/abs/pii/S1352231099004604.*
>
> *3. These products may be packaged in a variety of materials, many of which are reusable, such as cardboard, glass, and plastic, which are materials for recycling and processing industries. Therefore, under the principles of the circular economy, their final disposal should be minimized, and they should be reintroduced into production cycles. This is how this Ministry, together with MINAE and other institutional actors, participates in the development and monitoring of the National Circular Economy Policy and Strategy.*
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> *4. The aforementioned products must be categorized and handled separately by authorized waste managers, in accordance with Decree 37567-SMINAET-H, in line with the waste management priority hierarchy established in Article 4 of Law 8839 on Comprehensive Waste Management.*
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> *5. Therefore, the proposed regulation strengthens control over physical, chemical, biological, and social factors that affect the human environment by reducing material waste and promoting sustainable environmental practices throughout the product life cycle. This not only protects people's health, but also preserves natural resources and promotes a more sustainable future for generations to come."*

16.- That in relation to the provisions of Article 52, paragraph b) of Law No. 10473 of April 24, 2024, "National Quality System," this regulation complies with the technical criteria regarding the draft technical regulations that the Executive Branch wishes to implement, in accordance with Official Letter No. CARTA-MEIC-067-2025 of April 29, 2025, issued by the National Council for

Technical Regulation (CONART in Spanish), led and coordinated by the Ministry of Economy, Industry, and Trade, for the purpose of being submitted for public consultation.

17.- That this Executive Decree was submitted for national and international public consultation through notice No. MS-AJ-FG-1415-2025, published on the official website of the Ministry of Health, for the period from June 4 to August 5, 2025, in accordance with Article 70 of Executive Decree No. 44908-MEIC of January 21, 2025, "Regulations for Chapters I and II, Section I of Chapter V of the National Quality System Law."

18.- That this Executive Decree was notified to the World Trade Organization, under reference G/TBT/N/CRI/205, for a period of 60 calendar days, which expired on August 5, 2025, and as a result of this international consultation, comments were received from third-party trading partners, which were addressed, as recorded in the MEIC's prior control platform, known as SICOPRE.

19. That in accordance with the provisions of Article 361 of Law No. 6227 of May 2, 1978, "General Law on Public Administration," this Executive Decree was submitted for public consultation to citizens and interested parties on the virtual platform of the Prior Control System (SICOPRE for its acronym in Spanish) of the Ministry of Economy, Industry, and Commerce. As a result of this process, the comments received were analyzed.

20.- That in accordance with the provisions of Article 12 bis of Executive Decree No. 37045-MP-MEIC of February 22, 2012, "Regulations to the Law on Protection of Citizens from Excessive Requirements and Administrative Procedures" and its amendment, this regulation complies with the principles of regulatory improvement, in accordance with the favorable report No. DMR-DARINF-226-2025 of October 8, 2025, issued by the Directorate of Regulatory Improvement of the Ministry of Economy, Industry, and Commerce.

21.- That pursuant to Article 72 of Executive Decree No. 44908-MEIC of January 21, 2025, "Regulations for Chapters I and II, Section I of Chapter V of the National Quality System Law," the Technical Secretariat of the National Council for Technical Regulation (Conart for its acronym in Spanish), coordinated by the Ministry of Economy, Industry, and Commerce, informs the Ministry of Health that the implementation of this Executive Decree may continue, according to official letter No. CARTA-MEIC-DIREVI-STCONART-019-2025 dated October 29, 2025.

THEREFORE,

THEY DECREE:

Article 1-The following technical regulation is approved:

TECHNICAL REGULATION RTCR 519-2025. HEALTH RISK PRODUCTS. VAPING PRODUCTS. ADMINISTRATIVE NOTIFICATION OF VAPING LIQUIDS, LABELING, AND CONTROL

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1. PURPOSE.

To establish the technical specifications that vaping liquids must comply with and the requirements under which administrative notification, labeling, and control will be carried out, as well as the prohibition of advertising, promotion, and sponsorship of such liquids, and the disposal of waste.

2. SCOPE OF APPLICATION.

This decree applies to all vaping liquids sold in the country, whether imported or manufactured in Costa Rica. The provisions established in these regulations are mandatory for individuals or legal entities engaged in the manufacture, repackaging, storage, import, marketing, distribution, sale of nicotine and nicotine-free vaping liquids, and waste disposal.

3. REFERENCES.

These technical regulations do not make reference to any other regulations.

4. DEFINITIONS.

4.1. Aerosol: Suspension of ultramicroscopic particles of solids or liquids in air or another gas.

4.2. Scope of accreditation: Specific conformity assessment activities for which accreditation is intended or has been granted.

4.3. Campaign: For the purposes of these regulations, a campaign is understood to be each of the annual periods in which manufacturers, importers, and distributors of vaping liquids must incorporate the health messages and warnings established by the Ministry of Health on the primary and secondary packaging of vaping liquids.

4.4. Cannabis: Any herbaceous plant of the genus cannabis (Cannabaceae family), including its seeds, leaves, flowering tops, or fruit, and any other plant material derived from it.

4.5. Cannabidiol: A non-psychoactive cannabinoid with medical applications, contained in the cannabis plant.

4.6. Control: Inspection activity carried out to ensure effective compliance with the provisions contained in these regulations.

4.7. Disposable devices: These are devices consisting of an electronic part (Mod) attached to a cartridge containing liquid, which is discarded after use.

4.8. Distributor: Any natural or legal person, national or foreign, de facto or de jure entity, habitually engaged in the wholesale or retail distribution or marketing of vaping liquid.

4.9. Primary packaging: Any container that comes into direct contact with the vaping liquid, in order to protect it from deterioration, contamination, or adulteration and to facilitate its handling.

4.10. Secondary packaging: Any container that holds one or more primary packages to protect them and make it easier to sell them to the end consumer. Secondary packaging is usually used to group several primary packages into a single sales unit.

4.11. Supplementary label: A label used to provide consumers with mandatory information when the original label is in a language other than Spanish, or to add mandatory elements not included in the original label and required by these regulations.

4.12. Conformity assessment: Activity that allows the demonstration of compliance with specified requirements relating to a product, process, system, person, or body.

4.13. Manufacturer: Natural or legal person engaged in the manufacture of liquids used in ENDS and ENNDS.

4.14. Safety data sheet (SDS): Source of information for chemical product management, which must comply with the information established in the Globally Harmonized System (GHS) in its current version and must not be more than five years old from the date of issue or last revision. The content of the Safety Data Sheet, the guidelines for its preparation, and the specification of its content can be found in Annex 4 of the GHS, tenth edition.

4.15. Qualitative and quantitative formula: List of ingredients in a vaping liquid, issued by the manufacturer with their respective quantities or concentrations.

4.16. Hexahydrocannabinol: A substance generated from a chemical process that modifies the basic structure of tetrahydrocannabinol (THC).

4.17. Importer: Natural or legal person authorized by the manufacturer of the vaping liquid to import their product.

4.18. Influencer: A person or public figure with the ability to influence the decisions of their audience, mainly through social media, as well as any other means of communication.

4.19. Testing laboratory: A site where operations/tests and/or sampling are carried out to identify and/or measure the characteristics of a given product, process, or service using a specific method.

4.20. Vaping liquid: Liquid solution or similar contained in a capsule or container, pre-filled and sealed or refillable, with or without nicotine, to be heated and converted into vapor by the ENDS/ENNDS.

4.21. Detection limit: Minimum concentration of an analyte in a sample matrix that can be detected, but not necessarily quantified, under specific analytical conditions.

4.22. Test method: Document detailing a set of operations, described specifically, for performing particular measurements with respect to the characteristics of an item.

4.23. Non-standardized method: Method developed by a third party (non-internationally recognized body), or which has been adapted by the laboratory from a standardized method.

Note: The development and adaptation of the method include the validation stage.

4.24. Standardized method: Method developed by a standardization body or other internationally recognized body, whose methods are generally accepted by the relevant technical sector.

4.25. Modified standard method: A standard method to which, for various reasons, one or more modifications have been made that could significantly influence the results obtained.

Note 1: Any change to a standard method must be analyzed, and its effect on the results obtained must be technically demonstrated; this must be duly documented.

Note 2: Before using a modified method, it must be validated.

4.26. Sample: A finite part or portion extracted from a set that is considered representative of the whole and that is taken or separated from it using certain methods for study, analysis, or experimentation.

4.27. Nicotine: An organic compound, an alkaloid found mainly in the tobacco plant (Nicotiana tabacum), which can be obtained from tobacco leaves or produced synthetically in a laboratory.

4.28. INTE-ISO/IEC 17025 standard: International standard that establishes the general requirements for competence in performing tests or calibrations, including sampling. It covers tests and calibrations performed using standardized, non-standardized, modified standardized, and laboratory-developed methods. It applies to all organizations that perform tests or calibrations, as well as to laboratories where tests or calibrations are part of product inspection and certification.

4.29. Administrative notification: The act by which the administrator declares the composition, characteristics, and labeling of vaping liquids that are manufactured, packaged, and marketed in the country and for which they assume responsibility before the Ministry of Health.

4.30. Conformity Assessment Bodies: Bodies that perform conformity assessment services, which may be public or private, domestic or foreign.

4.31. Sponsorship: Any form of contribution to any event, activity, or individual with the purpose, effect, or potential effect of directly or indirectly promoting a nicotine-containing or nicotine-free vaping liquid or any other nicotine delivery product.

4.32. Complementary products: Other substances or additives used to give flavor and/or taste to vaping liquids and that do not contain nicotine.

4.33. Health risk product: Chemical or natural substances or mixtures thereof, the consumption of which requires regulation by the Ministry of Health because they have an intrinsic risk of causing a harmful effect on human health, the severity of which depends on the amount, frequency, and form of consumption.

4.34. Advertising and promotion: Any form of communication, recommendation, or commercial action with the purpose, effect, or potential effect of promoting, directly or indirectly, a vaping liquid or accessory.

4.35. Electronic Nicotine Delivery Systems (ENDS): Electronic devices or equipment for heating a liquid formula containing nicotine, which generates an aerosol or vapor that can be inhaled.

4.36. Electronic Non-Nicotine Delivery systems (ENNDS): Electronic devices or equipment for heating a nicotine-free liquid formula that generates an aerosol or vapor that can be inhaled.

4.37. Similar technologies: Products that emit nicotine and other chemicals, which users inhale or ingest, releasing the nicotine and other additives. They may or may not be flavored. They mimic the habit of smoking conventional cigarettes, and some are used orally.

4.38. Tetrahydrocannabinol: The psychoactive component (alteration of perception and mood modification) of the cannabis plant that is most important and abundant in varieties classified precisely as psychoactive.

4.39. Vaporizer: Electronic device for vaping. Person who vapes.

4.40. Vaping: The action of producing vapor from the gasification of vaping liquid through the action of heat generated by Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS) when inhaled and/or exhaled.

4.41. Vapor: Gaseous fluid whose temperature is below its critical temperature. Its pressure does not increase when compressed, but rather partially transforms into liquid.

5. ABBREVIATIONS.

5.1. AOAC: Association of Official Analytical Collaboration.

5.2. ASTM: American Society for Testing and Materials.

5.3. CAS: Numerical designation assigned to chemical substances by the Chemical Abstracts Service (CAS) in the US. Each individual number allows for the unambiguous identification of a substance.

5.4. CBD: Cannabidiol.

5.5 DRPIRS: Directorate for the Regulation of Products of Interest and Health Risk of the Ministry of Health.

5.6. ECA: Costa Rican Accreditation Entity.

5.7. HHC. Hexahydrocannabinol.

5.8. IAFA: Institute on Alcoholism and Drug Dependence.

5.9. INCIENSA: Costa Rican Institute for Research and Teaching in Nutrition and Health.

5.10. INTECO: Costa Rican Institute of Technical Standards.

5.11. ISO: International Organization for Standardization.

5.12. IUPAC: International Union of Pure and Applied Chemistry.

5.13. PRS: Health Risk Product.

5.14. ENDS: Electronic Nicotine Delivery Systems.

5.15. ENNDS: Electronic Non-Nicotine Delivery Systems.

5.16. THC: Tetrahydrocannabinol.

6. SPECIFICATIONS THAT VAPING LIQUIDS MUST MEET.

6.1. General specifications.

6.1.1. Refillable vaping liquid containers or cartridges must have opening systems, caps, or closures specially designed to prevent children from opening the container and must have mechanisms that ensure the device can be refilled without leakage, as well as the respective instructions for use in Spanish.

6.1.2. The concentration level of liquids for ENDS marketed or manufactured in the national territory must be less than 20 mg/mL of nicotine.

6.1.3. Domestic or imported products that are not registered with the Ministry of Health must be confiscated and destroyed by the health authorities. In the case of imports, will not be authorized for release from storage for entry into the country.

6.1.4. Vaping liquids must comply with the following specifications for the tests set out in section 10.2 of these regulations:

Test	**Specification**
Nicotine content (where applicable)	Not greater than 20 mg/mL
pH 5–7	Glycerin content 50–70%
Propylene glycol content	30–50%
Density	1.13 g/mL–1.19 g/mL
Determination of the presence of carbonyl compounds: Diacetyl, 2,3-pentadione, ethylene glycol, formaldehyde, acetaldehyde, acrolein	Below the detection limit of the analytical method
Determination of the presence of heavy metals: Cadmium, arsenic, lead, antimony, and mercury	Below the detection limit of the analytical method

The specifications indicated above may be modified by Executive Decree, in accordance with objective scientific criteria and international standards.

6.2. Declaration of ingredients present in the vaping liquid.

6.2.1. The importer or manufacturer of containers with vaping liquids, refillable cartridges, and disposable nicotine vaping devices must submit the qualitative and quantitative formula of the vaping liquid and must declare all substances present in the product to be marketed using the common name of each substance and its CAS number, without using abbreviations (also include substances with high health risks such as heavy metals).

6.2.2. The Ministry of Health may prohibit the use of certain ingredients by Executive Decree, provided that it is demonstrated, in accordance with objective scientific criteria and international standards, that these ingredients increase the overall inherent toxicity and dependence on vaping liquids.

6.3. Prohibitions on vaping liquids.

6.3.1. The manufacture, repackaging, storage, importation, marketing, distribution, and sale of vaping liquids containing the following are prohibited throughout the national territory:

a) Vitamins, probiotics, minerals, natural cannabinoids (with the exception of products authorized for medicinal purposes in accordance with the regulations issued for that purpose) or synthetic cannabinoids (e.g., CBD, THC, HHC), active ingredients, concentrates, and extracts from plants or other substances that give the impression that the vaping liquid has health benefits or reduces health risks;
b) Caffeine, taurine, and other stimulant substances or compounds associated with energy and vitality.
c) Amino acids and/or proteins.
d) Fatty acids.
e) Flavorings, except those listed in Annex D of these regulations.
f) Glucuronolactone.
g) Metals, including cadmium, antimony, chromium, iron, lead, arsenic, mercury, and nickel.
h) Substances with coloring properties during combustion.
i) Substances that are carcinogenic, mutagenic, and toxic to reproduction (without the need for combustion).
j) Narcotics or psychotropic substances and products capable of producing physical or psychological dependence in people.
k) Precursors or essential chemicals: in accordance with the provisions of Law No. 7786 of April 30, 1998, on narcotics, psychotropic substances, unauthorized drugs, related activities, money laundering, and terrorist financing, comprehensively amended by Law No. 8204 of December 26, 2001, of the same name.
l) Diacetyl.
m) 2,3-pentadione.
n) Ethylene glycol.
o) Formaldehyde.
p) Acetaldehyde.
q) Acrolein.
r) Flavorings, substances to impart odor.

To verify the above in the case of substances that should not be present in vaping liquids, the result of the determination test must be below the detection limit of the method used or show no presence in the case of identification tests.

6.3.2. The sale of nicotine-containing vaping liquids in refillable containers or cartridges larger than 10 mL and non-nicotine vaping liquids in refillable containers or cartridges larger than 20 mL is not permitted.

6.3.3. ENDS, ENNDS, capsules, or liquid containers with or without nicotine that contain additives, materials, or chemicals in their physical elements that cause them to possess or emit aromas reminiscent of desserts, fruits, spices, or other odors that generate pleasure or are attractive to people are not permitted in the national territory.

7. LABELING.

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7.1. General provisions for the labeling of vaping liquids and the devices that contain them.

7.1.1. The use of shapes or images related to food, fruit, spices, and desserts, toy shapes, influencers, artists, athletes, intellectuals, scientists, or professionals who are generally well-known to people of fame or with special abilities, characters, logos, or flags of sports teams, fictional characters, or other information that confuses the consumer or makes the product more attractive or eye-catching.

7.1.2. Inside the primary packaging of vaping liquids, an insert must be included detailing, in Spanish, the health risks attributable to the consumption of this type of device. If necessary, this insert may be foldable so that it fits into small packages. In cases where it is not possible to open the primary packaging to insert the insert, the insert must be affixed in such a way that it remains in the packaging for consumer review, without totally or partially obscuring the health warnings on the product.

7.1.3. The information that must appear on the label, pursuant to this technical regulation, must be indicated in characters that are legible, visible, indelible, and easy to read by the consumer under normal circumstances of purchase and use.

7.1.4. The label must be written in Spanish. When the language in which it is written is not Spanish, a complementary or adhesive label must be used that contains the mandatory information in that language.

7.1.5. Terms such as “low risk,” “alternative product to quit smoking,” “low nicotine,” “Light,” “Ultralight,” “Mild,” “extra,” and “ultra,” as well as any other terms that may lead the public to believe that a vaping product is less harmful than another in terms of its content, risks, or emissions, should not be used.

7.1.6. The supplementary label added to the product must not obscure the following technical information on the original label:

a) Batch number.
b) Net content (of the vaping liquid).
c) Number of puffs (pulses or actions of the device).
d) Notification number issued by the Ministry of Health.

7.1.7. The labeling of vaping liquids and devices containing them must not use phrases, images, or any other form of message that promotes consumption in a misleading, false, or deceptive manner.

7.1.8. Manufacturers, importers, and distributors of vaping liquids and devices containing them must adapt the packaging of vaping liquids in any form intended for the end consumer to the provisions established in this regulation.

7.1.9. For all vaping liquids and devices containing them, their labeling shall comply with the provisions of this regulation.

7.1.9.1. Labeling for primary packaging: All primary packaging of vaping products marketed in the national territory must comply with the following provisions:

a) Fifty percent (50%) of the lower part of the main surfaces or sides must be used to permanently print in color the health warnings established by the Ministry of Health. Each product package shall use a different design on each of the main sides.
b) Each primary package of the products must include a different health message on the lower part of each of the main faces, which will be rotated. During each annual rotation period, the health warnings established by the Ministry of Health will circulate in the market. For this purpose, the following provisions shall apply:

b.1. They shall be distributed proportionally, in a uniform and simultaneous manner, to the volume of the primary packaging.

b.2. Health warnings must be printed in colors that are as close as possible to the colors specified and as clearly as possible.

b.3. Health warnings must not be obscured by other information on the packaging.

b.4. They must be placed in such a way that the normal opening of the package does not damage or permanently obscure the text or image of the health warning.

c) The following statements must be placed in a space that does not affect the space specifically designated for health warnings: “For sale exclusively in Costa Rica,” “Sale prohibited to minors,” and “Keep out of reach of children.” The font must be Arial No. 12, contrasting with the image or pictogram background color so that it is clearly visible and legible.
d) Health warnings must appear on 100% of one of the side faces of the primary packaging, printed legibly in Arial No. 12 font, in uppercase letters, contrasting with the colors of the package and allowing for easy reading. Likewise, this qualitative information on the contents of the products and their emissions must be rotated and must contain warnings such as: (When you vape, you are exposed to chemicals that could affect your health). Manufacturers, importers, and distributors of ENDS and ENNDS must adapt the packaging of products in any form intended for the end consumer to the provisions established in this regulation. The sale and distribution of any product that does not comply with the provisions established herein will not be permitted.
e) The primary packaging of products must include the following printed information:

e.1. Product brand.

e.2. Net content of product units, country of origin or provenance, batch number.

e.3. Information on the manufacturer, distributor, and importer, without prejudice to any health warnings previously approved by the Ministry of Health.

f) In the case of imported products, the information contained on the label must appear in Spanish, comply with the above requirements, and be printed on the packaging.

7.1.9.2. Labeling for secondary packaging: All secondary packaging for vaping liquids sold in the country must comply with the following provisions:

a) Secondary packaging must be made of cellophane or a colorless material that does not obstruct the visibility and legibility of the health messages on the units it contains and other information established on the primary packaging.
b) If secondary packaging is used that obstructs the visibility of the primary packaging, it must contain the same requirements established for primary labeling.

7.1.9.3. The Ministry of Health shall establish, by ministerial resolution to be published in the Official Gazette, the designs of the messages and health warnings to be used in each of the campaigns, including the characteristics of the font, size, and background color of the image or pictogram, which must be printed on the primary and secondary packaging by manufacturers, importers, and distributors of vaping liquids. The Ministry of Health shall notify manufacturers, importers, and distributors of vaping liquids of these designs 12 months prior to the new designs coming into effect. From the date the new designs take effect, a non-extendable six-month transition period is established between the two campaigns, during which both the previous and new designs established by the Ministry of Health may be used.

7.2. Labeling requirements. The primary packaging of vaping liquids and ENNDS must be printed in Spanish with:

a) The commercial name of the product and brand.
b) The administrative notification number from the Ministry of Health.
c) A list of ingredients in descending order of mass (weight).
d) Nicotine concentration in mg/mL (where applicable).
e) Name of manufacturer and country of origin.
f) Name of importer, address, and telephone number.
g) Batch number.
h) Net content (in mL).

7.2.1. In the case of vaping liquids and ENNDS in packaging that makes complete labeling difficult, the primary packaging must contain the information in sections a), b), and d) of section 7.2 of these regulations; the information not included must be included either on the secondary packaging and the product must be supplied to the consumer with said secondary packaging; or on the supplementary label.

8. SAMPLE TAKING AND SAMPLING.

8.1. To assess compliance with the parameters established in this technical regulation, the Ministry of Health shall take random and representative samples of vaping liquids at points of sale or in the warehouses of the national manufacturer, importer, or distributor in order to verify compliance with the provisions of this technical regulation. Sampling shall generally comprise the following stages:

a) Selection and collection of the sample and counter-sample at the establishments subject to control.

b) Identification and registration of both to ensure their traceability.
c) Packaging and transport under conditions that preserve their integrity.
d) Delivery and custody at the official laboratory or the corresponding Directorate, in accordance with current institutional provisions.

8.2. All manufacturers, importers, distributors, or marketers of vaping liquids must allow access to products and establishments and provide the information requested by Ministry of Health inspectors within the specified time frame.

9. ANALYSIS METHODS FOR VAPING LIQUIDS WITH AND WITHOUT NICOTINE.

The testing laboratory that carries out the tests to verify compliance with the provisions set forth in this regulation must ensure that the method used to verify the requirements specified in this regulation complies with the particular requirements for the specific use and that the testing methods are based on verified standardized methods (Pharmacopoeias, INTECO, ISO, ASTM, AOAC) or, failing that, on validated non-standardized test methods or methods from competent bodies in this field.

10. CONFORMITY ASSESSMENT PROCEDURE.

10.1 Testing laboratories. INCIENSA is declared the official laboratory for the control of products regulated by this technical regulation. However, the Ministry of Health may, if necessary, contract with public or private Conformity Assessment Bodies accredited under the INTE-ISO/IEC 17025 standard “General requirements for the competence of testing and calibration laboratories” in its current version to carry out tests or verifications prior to marketing or on the market.

The official laboratory, as well as the testing laboratories that carry out tests to verify the provisions of section 6.1.4 of these regulations, must comply with the provisions of articles 39, 41, and 42 of Law No. 10473 of April 24, 2024, “National Quality System Law,” and its regulations.

10.2. Pre-marketing analysis.

The importer or manufacturer of containers with vaping liquids, refillable cartridges, and disposable vaping devices with or without nicotine must comply with the specifications of section 6.1.4 of this regulation, for which they must submit, after issuing the corresponding administrative notification and prior to marketing on the domestic market, samples of a batch of the notified product to INCIENSA or the laboratory established by the Ministry of Health for analysis and verification of the following tests:

a) Determination of nicotine content (if applicable).
b) Determination of glycerin and propylene glycol.
c) Determination of pH and density.
d) Determination of the presence of carbonyl compounds: Diacetyl, 2,3-pentadione, Ethylene glycol, Formaldehyde, Acetaldehyde, Acrolein.

e) Determination of the presence of heavy metals: cadmium, arsenic, lead, antimony, and mercury.

The foregoing does not exempt the Ministry of Health from its duty to verify at any time the accuracy of the information provided in the sworn statement set forth in Annex A of these regulations.

The interested party, together with the samples for analysis prior to marketing, must complete the form contained in Annex C, Application form for analysis prior to marketing of these regulations.

The substances to be analyzed in vaping liquids prior to their marketing and sale may be modified by Executive Decree, in accordance with objective scientific criteria and international standards.

The number of samples required will be published on the Ministry of Health website.

The importer or manufacturer will cover the costs of these analyses. These amounts will be governed by the list of tests and their respective costs, which will be published on the Ministry of Health website and updated every two years by Executive Decree, taking into account the annual inflation rate determined by the Central Bank. The amount for the analyses to be performed must be deposited in the dollar or colón account of Trust 872-3, MINISTRY OF HEALTH, CT AMS-BNCR, before the samples are delivered to the official laboratory.

The bank accounts of the Ministry of Health Trust - CTAMS - Banco Nacional de Costa Rica, into which deposits should be made, are listed below:

a) Account in colones 000-213715-6 Trust 872-BNCR-Ministry of Health.
b) Account in US dollars 000-617477-5 Trust 872-BNCR-Ministry of Health.

The Ministry of Health will have 30 calendar days from receipt of the application for Administrative Notification of Raw Materials and Vaping Liquids to send the administrator the results of the analysis of the registered product.

10.3 Market surveillance.

The Ministry of Health shall carry out regular market checks on vaping liquids, refillable cartridges, and disposable vaping devices with or without nicotine, taking samples at points of sale or in the warehouses of the national manufacturer, importer, marketer, or distributor and perform analyses to verify the conformity of the products regulated in this technical regulation in accordance with the control plan defined by the Ministry of Health in coordination with the official laboratory or the contracted laboratory, if required.

In the case of compounds generated during the vaporization of vaping liquids, they will be monitored by the Ministry of Health, according to scientific contributions from the international community on the regulation of emerging substances in tobacco products.

The importer or manufacturer shall cover the costs of such analyses. These amounts shall be governed by the list of tests and their respective costs, which shall be published on the Ministry of Health's website and updated every two years by Executive Decree, taking into account the annual inflation rate determined by the Central Bank. The cost of the analyses performed must be deposited in the dollar or colon account of Trust 872-3, MINISTRY OF HEALTH, CT AMS-BNCR, within a period not exceeding one month from notification of the corresponding result.

The bank accounts of the Ministry of Health Trust - CTAMS - Banco Nacional de Costa Rica, into which deposits should be made, are listed below:

a) Account in colones 000-213715-6 Trust 872-BNCR-Ministry of Health.
b) Account in US dollars 000-617477-5 Trust 872-BNCR-Ministry of Health.

11. ADMINISTRATIVE NOTIFICATION OF RAW MATERIALS AND VAPING LIQUIDS.

11.1. General conditions of administrative notification.

11.1.1. Only the manufacture, repackaging, storage, importation, marketing, distribution, and sale of vaping liquids with or without nicotine that have been notified to the Ministry of Health shall be permitted.

11.1.2. All raw materials included in vaping liquids manufactured or imported into the national territory must be notified to the Ministry of Health.

11.1.3. The request for notification, renewal, or change after administrative notification of the submitted information must be processed before the DRPIRS.

11.1.4. The manufacturer, in the case of domestically manufactured products, or the importer, in the case of products manufactured abroad, as well as the distributor, must have a valid Health Operating Permit in accordance with the activity to be carried out.

11.1.5. The administrative notification is valid for five years.

11.2. Requirements for administrative notification, renewal, or post-administrative notification changes to vaping liquids and raw materials.

11.2.1. Attach the Vaping Liquid Notification Form in accordance with Annex A of these regulations, completed and signed by the manufacturer or importer. To allow the administration to verify that the components have not changed, the applicant must submit this form annually

throughout the period in which the marketing authorization is valid, referencing the date when the appropriate administrative notification was approved.

11.2.2. Attach the Sworn Declaration Form for the Raw Materials of Vaping Liquids contained in Annex B of these regulations, completed and signed by the manufacturer or importer of the raw materials, also providing the Safety Data Sheet for the raw materials in Spanish.

11.2.3. Qualitative and quantitative formula, using international nomenclature (IUPAC) and indicating the concentration of nicotine, glycerin, propylene glycol, and other ingredients, issued by the manufacturer. If it is issued in a language other than Spanish, an official translation must be provided. This document must also be legalized or apostilled if it is issued abroad.

11.2.4. Original labeling and its translation into Spanish. When the language in which the original label is written is not Spanish, a supplementary label containing the mandatory information must be affixed.

11.2.5. Proof of payment of $300 (three hundred dollars), the fee established by the Ministry of Health for administrative notification and renewal procedures, $100 (one hundred dollars) for changes after notification of vaping liquids, and $50 for notification of raw materials. The amount must be deposited in the dollar or colón account of Trust 872-3, MINISTRY OF HEALTH, CTAMS-BNCR, or using the authorized means if a digital system is implemented to carry out the administrative notification procedure.

The bank accounts of the Ministry of Health Trust Fund - CTAMS - Banco Nacional de Costa Rica, into which deposits should be made, are listed below:

a) Account in colones 000-213715-6 Trust Fund 872-BNCR-Ministry of Health.

b) Account in US dollars 000-617477-5 Trust 872-BNCR-Ministry of Health.

11.2.6. Toxicological information.

11.2.7. The interested party must submit the application to the DRPIRS, with the requirements established in sections 11.2.1 to 11.2.6 of these regulations.

The respective notification shall be sent to the email address provided by the applicant within 15 calendar days. This period shall begin on the day following the submission of the application and verification of the completeness of the requested documents.

11.2.8 If the DRPIRS finds any discrepancies during the verification of the documents and information submitted, the applicant shall be notified once. This notification suspends the application's resolution deadline and gives the applicant up to 10 business days to comply with the notification; after this period, the remaining deadline for resolving the application will continue to be counted.

If it is verified that the omissions have been corrected, the DRPIRS will issue the administrative notification and send it to the applicant.

In cases where no response is received from the applicant to the aforementioned notification, or if the documentation received does not comply with the provisions, the DRPIRS issues a resolution denying the administrative notification, which must state the reason for the rejection. This resolution must be notified to the interested party. The denial of the administrative notification terminates the procedure. The remedies established in Article 60 of Law No. 5412 of November 8, 1973, "Organic Law of the Ministry of Health," are available against the denial resolution.

12. CAUSES FOR CANCELLATION OF THE ADMINISTRATIVE NOTIFICATION.

The Ministry of Health shall proceed to cancel the administrative notification, following due process, in the following cases:

a) When the product does not comply with what is stated on the label.
b) Due to falsification or alteration of the documents used in the application.
c) When it is proven that the data and information contained in the file are incorrect or false.
d) When the concentrations of the declared components exceed those established in the manufacturer's specifications regarding the content of regulated substances.
e) When the product is marketed under conditions different from those notified.
f) When the Ministry of Health has banned the product or any of its ingredients, and they are present in the product.
g) When an alert is issued regarding the prohibition of the use of the product or any of its ingredients at the international level.
h) In the case of domestic manufacturing or distribution, when the Health Operating Permit has been canceled or has expired.
i) When non-compliance with the conditions under which the administrative notification was granted is demonstrated.
j) When substances other than those declared in the application are detected.
k) When the manufacturer or importer fails to pay the amount corresponding to the analyses carried out prior to or during marketing within the time frame and in the manner established by the Ministry of Health in sections 10.2 and 11.2.5 of these regulations.

13. ADVERTISING, PROMOTION, AND SPONSORSHIP

Any form of advertising, promotion, and sponsorship of ENDS and ENNDS, including their liquids, as well as electronic devices that use heated tobacco and similar technologies, is prohibited. This prohibition includes advertising, promotion, and sponsorship at points of sale; marketing in any media; and any efforts within the distribution chain. It also includes the main forms of marketing, such as advertising, sales promotion, personal selling, public relations, database marketing, sponsorship marketing, alternative marketing, interactive electronic marketing, and marketing of

experiences and events, both public and private. This includes any promotional activity on websites, mobile apps, social media, or those carried out by influencers, presenters, or guests in any media. The ban includes brand mentions, displays, and the use of such devices.

14. OTHER PROHIBITIONS RELATING TO THE SALE AND SUPPLY OF ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS), ELECTRONIC NON-NICOTINE DELIVERY SYSTEMS (ENNDS), SIMILAR TECHNOLOGIES, AND VAPING LIQUIDS.

14.1. Sales to consumers by telephone, digital, electronic, internet, mail, or other means by which the identification of the purchaser as an adult cannot be clearly and promptly verified, as well as street vending and similar sales, are strictly prohibited.

14.2. The use of vending machines or dispensers for ENDS, ENNDS, and vaping liquids is prohibited.

14.3. When the sale of ENDS and ENNDS, including the liquid for their use, is carried out at a physical point of sale, it must be done exclusively at the checkout counters.

15. DISPOSAL OF WASTE RELATED TO VAPING LIQUIDS

Waste generated by a manufacturer, importer, or distributor related to vaping liquids, including raw materials, packaging materials, and batteries, must be disposed of according to its category and in accordance with Law No. 8839 of June 24, 2010 “Law for Comprehensive Waste Management” and Executive Decree No. 37567-S-MINAET-H of November 2, 2012, “General Regulations for the Law for Comprehensive Waste Management.” In the event of proven non-compliance, the penalties established in Articles 52 to 57 of the aforementioned Law shall apply.

Regarding wastewater and environmental pollution by other waste that cannot be classified as solid waste, the provisions of Article 1 of the aforementioned Executive Decree No. 37567-S-MINAET-H shall apply.

16. CONFORMITY.

This document does not overlap with any international standard, as no particular standard existed at the time these regulations were drafted.

17. BIBLIOGRAPHY.

17.1. Conference of the Parties to the WHO Framework Convention on Tobacco Control. Electronic nicotine delivery systems and similar nicotine-free systems [Internet]. 2016. Available at: https://fctc.who.int/es/news-and-resources/publications/i/item/fctc-cop-7-11-electronic-nicotine-delivery-systems-and-electronic-non-nicotine-delivery-systems-(endsennds)-of-the-who-framework-convention-on-tobacco-control-of-the-seventh-session-of-the-conference-of-the-parties-(cop7).

17.2. Directive 2014/40/EU. On the approximation of the laws, regulations, and administrative provisions of the Member States concerning the manufacture, presentation, and sale of tobacco and related products, and repealing Directive 2001/37/EC. Brussels, Belgium.

17.3. National Federation of Departments. Colombia. Estudio para el diseño de un marco regulatorio en Colombia de los productos de tabaco calentado, cigarrillos electrónicos y sistemas similares con y sin nicotina ["Colombia. Study for the design of a regulatory framework in Colombia for heated tobacco products, electronic cigarettes, and similar systems with and without nicotine"], June 2022.

17.4. Government of Canada (1997). Tobacco and Vaping Products Act (TVPA). An Act to regulate the manufacture, sale, labeling, and promotion of tobacco products and vaping products.

17.5. MHRA (Medicines and Healthcare products Regulatory Agency) (2022). Guidance on the submission and content of notifications for Great Britain. Guidance Chapter 6 – Ingredient Guidance - Great Britain Advice on ingredients in nicotine-containing liquids in electronic cigarettes and refill containers.

17.6. National Institute for Public Health and the Environment, RIVM (2023). Reducing the attractiveness of e-liquids to youth: a proposal for a restrictive list of tobacco-related flavoring ingredients.

Unofficial Translation

ANNEX A (Regulatory)
SWORN STATEMENT FORM FOR THE INGREDIENTS OF VAPING LIQUIDS

REPUBLIC OF COSTA RICA MINISTRY OF HEALTH	NOTIFICACION NUMBER:

SWORN STATEMENT OF INGREDIENTS IN VAPING LIQUID

1. MANUFACTURING OR IMPORTING COMPANY	
1.1 Company name or full name	1.2 Legal entity ID number or natural person ID number:
1.3 Phone(s)	1.4 Email addresses
1.5 Form of notification	1.6 Signature (*)

I agree to submit this sworn statement of ingredients for vaping liquids annually.

2. – LEGAL REPRESENTATIVE OF THE MANUFACTURING OR IMPORTING COMPANY	
2.1 Full name	2.2 ID number
2.3 Phone(s)	2.5 Email address
2.6 Exact address for notifications	2.7. Signature (*)

3. PRODUCT INFORMATION
3.1 Product Name and Brand
3.2 Product Presentation

4. NICOTINE, GLYCERIN, AND PROPYLENE GLYCOL LEVELS

INGREDIENTS	CAS NUMBER	CONCENTRATION (g/mL)	METHOD OF ANALYSIS
NICOTINE			
GLYCERIN			
PROPYLENE GLYCOL			
INGREDIENTS (signed attached sheet)			

FOR THE EXCLUSIVE USE OF THE MINISTRY OF HEALTH

5. DATE OF RECEIPT

6. NAME AND SIGNATURE OF THE OFFICIAL RECEIVING THE DOCUMENT

Unofficial Translation

(*) This information is a sworn statement, in accordance with the penalties imposed by the Penal Code for the crime of perjury. **By signing this document, the legal representative attests that everything stated herein and in the attached documents is true, and furthermore, they sign this document, aware of the value, scope, and significance of these statements.**

Unofficial Translation

ANNEX B (Regulatory)
SWORN STATEMENT REGARDING THE RAW MATERIALS USED IN VAPING LIQUIDS

REPUBLIC OF COSTA RICA **MINISTRY OF HEALTH**	**NOTIFICATION NUMBER:**

SWORN STATEMENT REGARDING THE RAW MATERIALS USED IN VAPING LIQUIDS

1. MANUFACTURER OR IMPORTER OF THE RAW MATERIAL	
1.1 Company name or full name	1.2 Legal entity ID number or natural person ID number:
1.3 Phone(s)	1.4 Email address for notifications
1.5 Exact address	1.6 Signature (*)
2. – LEGAL REPRESENTATIVE OF THE MANUFACTURING OR IMPORTING COMPANY	
2.1 Full name	2.2 ID number
2.3 Phone(s)	2.4 Email address
2.5 Exact address for notifications	2.6. Signature (*)
3. RAW MATERIAL INFORMATION	
3.1 Raw material name	
3.2 CAS number	
3.2 Presentations	
FOR THE EXCLUSIVE USE OF THE MINISTRY OF HEALTH	
6. DATE OF RECEIPT	
7. NAME AND SIGNATURE OF THE OFFICIAL RECEIVING THE DOCUMENT	

(*) This information is a sworn statement, in accordance with the penalties imposed by the Penal Code for the crime of perjury. **By signing this document, the legal representative attests that everything stated herein and in the attached documents is true, and furthermore, they sign this document, aware of the value, scope, and significance of these statements.**

Unofficial Translation

ANNEX C (Regulatory)
PRE-MARKET ANALYSIS APPLICATION FORM

REPUBLIC OF COSTA RICA **MINISTRY OF HEALTH**
REQUEST FOR PRE-MARKETING ANALYSIS
1. LEGAL REPRESENTATIVE OF THE MANUFACTURING OR IMPORTING COMPANY / MANUFACTURING OR IMPORTING COMPANY

1.4 Company name or full name	1.5 Legal entity ID number or natural person ID number
1.6 Email address for notifications	
1.7 Health Permit Number	

3. PRODUCT INFORMATION
3.1 Notification number 3.2 Name of product and brand
FOR THE EXCLUSIVE USE OF INCIENSA
6. DATE OF RECEIPT:
7. NAME AND SIGNATURE OF THE OFFICIAL RECEIVING THE DOCUMENT
(*) This information is a sworn statement, in accordance with the penalties imposed by the Penal Code for the crime of perjury. **By signing this document, the legal representative attests that everything stated herein and in the attached documents is true, and furthermore, they sign this document, aware of the value, scope, and significance of these statements.**

Unofficial Translation

ANNEX D (Regulatory)
LIST OF FLAVORINGS PERMITTED IN VAPING LIQUIDS

CAS number	Flavoring name
35044-65-9	Beta-Damascone
23726-91-2	2-Butene-1-one, 1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-, (E)
23726-92-3	2-Butene-1-one, 1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-, (Z)
23696-85-7	2-Butene-1-one, 1-(2,6,6-trimethyl-1,3-cyclohexadien-1-yl)
23726-93-4	2-Butene-1-one, 1-(2,6,6-trimethyl-1,3-cyclohexadien-1-yl)-,(2E)
1125-21-9	2-Cyclohexene-1,4-dione, 2,6,6-trimethyl-
4883-60-7	2-Hydroxy-3,5,5-trimethyl-2-cyclohexenone
536-78-7	3-ethylpyridine
350-03-8	3-Acetylpyridine
91-10-1	2,6-dimethoxyphenol
67-47-0	5-(Hydroxymethyl)-2-furfural
591-12-8	alpha-angelic lactone/ 2(3H)-Furanone, 5-methyl-
503-74-2	3-methylbutanoic acid
1139-30-6	caryophyllene oxide
3738-00-9	Ambroxide
564-20-5	(3aR)-(+)-Sclareolide

END OF TECHNICAL REGULATION

Transitory Provision I: Holders of vaping liquids who submitted notifications to the Ministry of Health under the category of Non-Hazardous Chemical Products prior to the entry into force of these regulations shall have a period of nine months from the publication of this Executive Decree to submit the requirements established in section 11 of these regulations.

Transitory Provision II: Vaping liquids that obtain their notification prior to the publication of the first ministerial resolution establishing the designs and health warnings that manufacturers, importers, and distributors of vaping liquids must include on primary and secondary packaging shall have six months for implementation, counted from the publication in the Official Gazette of the ministerial resolution, indicated in section 7.1.9.3 of this regulation.

Article 2—Effective Date. This Executive Decree shall take effect six months after its publication in the Official Gazette.

Issued at the Office of the President of the Republic. San José, on the eighth day of January two thousand twenty-six.

Unofficial Translation

RODRIGO CHAVES ROBLES.—The Minister of Health, Dr. Mary Munive Angermüller.—1 time.—(D45479 - IN202601033346).