Title: Technical Standards for Tobacco-Free Nicotine-Containing Oral Pouches

1. Context

Tobacco-Free Nicotine-Containing Oral Pouches are a novel category of products requiring development of technical product specifications with the aim of ensuring the governance of product safety and quality. Tobacco Free Nicotine-Containing Oral Pouches contain zero tobacco. The proposed Standard will define the safety and quality-related technical requirements for Tobacco-Free Nicotine-Containing Oral Pouches for manufacturers. If these requirements are followed, regulators and consumers can be assured that safety and quality are maintained across products and batches and that compliance with these specifications are supported by documentary evidence and information. Currently there is no Standard in Kenya, or the African region to provide Quality Assurance procedures and controls to produce consistent high-quality products, hence there is a need for the development of standards to address these types of new products.

2. Objective

The objective of the Standard is to define safety and quality requirements for producers and importers of Tobacco-Free Nicotine-Containing Oral Pouches. With this standardization document it is hoped that regulation bodies are reassured that the product safety and quality is maintained and evidenced across all products and batches. The industry welcome product safety standards and regulation and the Standard can serve to underpin future regulation in Kenya and potentially beyond.

3. Project Scope

This Standard specifies the requirements for the manufacture and testing of the quality of Tobacco-Free Nicotine-Containing Oral Pouches by:

• providing guidance on the purity of ingredients in manufacture and toxicological assessment

• establishing specific criteria, recommendations and guidance for:

- ingredient requirements
- nicotine limits
- product information &
- labelling.

The Standard is intended for use by laboratories, and test houses engaged in the testing of Tobacco-Free Nicotine-Containing Oral Pouches.

This Standard is not intended to cover any form of other tobacco products including combustibles, nasal snuff and chewing tobacco. This Standard does not cover licensed medicinal nicotine products such as NRT (Nicotine Replacement Therapy).

Tobacco-Free Nicotine-Containing Oral Pouches are a new product category, requiring the establishment of robust product standards, to ensure the governance of product safety and quality. For guidance and as a basis for establishing standards for these Tobacco-Free Nicotine-Containing Oral Pouches, the following is attached:

ANNEX A – Swedish Standard SIS/TS 72:2020: Nicotine-Containing, Tobacco Free Oral Products – Safety and Quality Related Requirements

ANNEX B Pakistan Standard Specification PS:5468-2020: Nicotine Containing Tobacco-Free Oral Products

Overall positive impact on the community?

Currently in Kenya, there are no technical specifications or standards to ensure that Tobacco-Free Nicotine-Containing Oral Pouches are manufactured consistently, following product safety and quality standards. The establishment of the technical specification / Standard would serve several functions including:

1. Increase transparency and simplify comparison of similar products;
2. Establish commitment to, and ensure specific recommendations and guidance for product ingredient safety and quality;
3. Ensure that packaging and labelling is of global industry-standard, complies with global and National Standards and regulations with appropriate warning labels and product information,
4. Promote development of similar products and
5. Increase customer, stakeholder and consumer confidence in product category and quality.

Proposed Kenya Standard (KS) for Tobacco-Free Nicotine-Containing Oral Pouches

1. INTRODUCTION:

This document aims to ensure product and consumer safety requirements for nicotine-containing tobacco-free oral products. In meeting these requirements, regulators, consumers and the public at large can be reassured that safety and quality is maintained across products and batches. Compliance with this technical standard should be reliably demonstrated with documentary evidence and through providing appropriate information to consumers of the products.

2. SCOPE:

These Tobacco-Free Nicotine-Containing Oral Pouch Standards serve to give guidance on ingredient requirements, nicotine limits, product information and labelling and product certification requirements for Tobacco-Free Nicotine-Containing Oral Pouch Standards exclusively intended for oral use, where the recommended method of consumption results in uptake of nicotine via the oral mucosa.

The proposed standards are NOT applicable to pharmaceutical nicotine products licensed under the Pharmacy and Poisons Board regulations or the governed by the Pharmacy and Poisons Act.

3. PURPOSE:

The purpose of these proposed standards is to define the quality, safety and minimum technical requirements for Manufacturers in order to reassure the regulators and the consumers that Tobacco- Free Nicotine-Containing Oral Pouches meet the highest quality and safety for consumption.

Normative references:

Globally Harmonized System of Classification and Labelling of Chemicals (GHS), United Nations

European Pharmacopoeia, Nicotine Monograph (1452)

United States Pharmacopeia, Nicotine Monograph

CORESTA Recommended Method No. 69 (Determination of pH of Tobacco and Tobacco Products)

IARC Monographs on the Identification of Carcinogenic Hazards to Humans

(https://monographs.iarc.fr/list-of-classifications/)

NTP Report on Carcinogens (https://ntp.niehs.nih.gov/go/roc)

4. DEFINITIONS:

For the purposes of this document, the following definitions and abbreviations apply

4.1. Constituent

An individual chemical substance within an ingredient.

4.2. Tobacco-Free Nicotine-Containing Oral Pouches

Pre-portioned, product that contains nicotine compounds and typically flavouring and other ingredients, but which does not contain tobacco, exclusively intended for oral use and for uptake of the nicotine via the oral mucosa.

4.3. Nicotine

Chemical substance that is a psychoactive stimulant present in the Tobacco-free Nicotine-Containing Oral Pouches , also known chemically as 3-(1-Methyl-2-pyrrolidinyl) pyridine.

4.4. Pharmaceutical grade

Substance that is approved for use in humans or animals or for which a chemical purity standard has been established as the highest standard and exceeds 99% purity.

4.5. Globally Harmonized System (GHS)

Globally Harmonized System of Classification and Labelling of Chemicals that defines and classifies the hazards of chemical products and communicates health and safety information on labels and safety data sheets and ingredient of a product.

4.6. Ingredient

Any compound or mixture of compounds intentionally included in a Tobacco-Free Nicotine-Containing Oral Pouches.

4.7. Flavours

A chemical substance, extract or ingredient that alter or enhance/imparts a taste flavor or aroma to a Tobacco-Free Nicotine-Containing Oral Pouches.

4.8. Pouch

A white pre-portioned consumable containing nicotine but FREE from tobacco with NO combustion. The user puts a pouch between the upper lip and gum and leaves it there while the nicotine is being released and absorbed through the oral mucosa.

4.9. Manufacturer

The legal entity responsible for producing Tobacco-Free Nicotine-Containing Oral Pouches.

4.10. Importer

An organization that brings Tobacco-Free Nicotine-Containing Oral Pouches into a country from abroad for sale.

5. REQUIREMENTS FOR INGREDIENTS:

5.1. Consumable/Flavouring Information Disclosure

The manufacturer shall ensure they possess full disclosure of all ingredients used in the final Tobacco-Free Nicotine-Containing Oral Pouches including flavours used in the production. This is important and pivotal in the toxicological risk assessment to confirm there are no unwanted constituents in the final Tobacco-Free Nicotine-Containing Oral Pouches thus ensuring the highest quality of these products.

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Such disclosure shall contain the list of Ingredients and their level of use in the final Tobacco-Free Nicotine-Containing Oral Pouches.

5.2. Ingredient Quality

All ingoing ingredients of the modern oral blend must meet the specifications for components of food, food chemical codex specifications, or be of pharmaceutical grade. The fleece component shall meet the specifications for a food contact material.

Only pharmaceutical grade nicotine (USP or EU grade) as determined by the KEBS/EU standards (14520) should be used in the manufacturing of Tobacco-Free Nicotine-Containing Oral Pouches. Such grade should undergo batch testing with the relevant Standards Authority in launched markets.

Where applicable, disclosure of Halaal status/certification shall be included for Oral Pouches ingredients.

5.3. Excluded Ingredients

Ingredients shall not be used in the manufacture of any Tobacco-Free Nicotine Containing Oral
Pouches if they meet any of the following classification criteria of the GHS via the oral route of exposure:
-Carcinogenicity (category 1 or 2);
-Germ cell mutagenicity (category 1, 1A, 1B or 2);
-Toxic to reproduction (category 1, 1A or 1B, or effects on or via lactation)

Ingredients shall not be used in the manufacture of any Tobacco-Free Nicotine-Containing Oral Pouches if they have been identified as any of the following:
-classified as “Carcinogenic to humans” (Group 1), “Probably carcinogenic to humans” (Group 2a) or “Possibly carcinogenic to humans” (Group 2b) by the International Agency for Research on Cancer.
-Identified by the United States National Toxicology Program (NTP) as either “Known” or “Reasonably Anticipated To Be” human carcinogens.

Tobacco-Free Nicotine-Containing Oral Pouches shall not contain ingredients, materials or constituents from animal origin.

Alcohol shall not be present as an ingredient. If any alcohol/ethanol is used in the manufacturing of Tobacco-Free Nicotine-Containing Oral Pouches, this should be removed from the final product and potential residual levels shall be less than 0.5%.

5.4. Toxicological risk assessment

The producer shall ensure that the use of the ingredients in a final consumable is or has been subject to a toxicological risk assessment, to ensure the addition of ingredients does not increase the inherent risk of a nicotine product.. The toxicological risk assessment itself, or a summary thereof, shall be documented by the producer for each commercial product. Product changes and/or availability of critical new information/data on ingredients will prompt the generation of an updated toxicological risk assessment.

In order to determine the supportable level of ingredient use, the toxicological risk assessment shall assess the potential hazard associated with the ingredients and, where applicable, those of any undesirable constituents of natural ingredients (Table 1), as well as the expected exposure to the consumer. The expected exposure shall be based on reasonable and foreseeable use of the product.

Toxicological risk assessments ultimately rely on the expert assessments of competent risk assessors to interpret the different data sources and provide a final judgment of risk. Appropriately competent individuals and procedures shall therefore be involved in toxicological risk assessment.

Table 1. Toxicologically Undesirable Constituents that can be naturally present in Flavourings

Substance name	CAS number(s)
agaric acid	666-99-9
aloin	1415-73-2
capsaicin	404-86-4
hypericine	548-04-9
beta-asarone	5273-86-9
1-allyl-4-methoxybenzene, also known as estragole	140-67-0
hydrocyanic acid	3017-23-0
menthofuran	494-90-6
4-allyl-1,2-dimethoxy-benzene, also known as methyleugenol	93-15-2
pulegone	89-82-7; 15932-80-6
quassin	76-78-8
1-allyl-3,4-methylenedioxybenzene, also known as safrole	94-59-7
teucrin A	12798-51-5
thujone (alpha and beta)	546-80-5; 76231-76-0
1,2-benzopyrone, also known as coumarin	91-64-5

5.5. Undesirable Constituents

Where toxicological undesirable constituents that can be naturally present in flavourings mentioned in Table 1, enter as constituents of natural flavours, the presence of these undesirable constituents in the final Consumable shall be restricted to levels deemed supportable by the toxicological risk assessment. This can be done through controlling their limited presence in natural flavourings or by limiting the inclusion level of natural flavourings containing undesirable constituents in the Consumable.

5.6. Allergens and Contact Sensitizers

Although Tobacco- Free Nicotine-Containing Oral Pouches are not intended for ingestion, they are intended to be held in the mouth for a certain period of time. It is possible that such oral exposure in people who have food allergies or intolerances, may elicit adverse effects. Therefore, analogous to food regulation the use of any ingredient or processing aid in the production of the product, that is a known food allergen, should be clearly marked on the product packaging. This is to ensure that consumers are adequately warned and can make an informed choice before purchase and use of the product. The manufacturer shall disclose any substances or constituents of Tobacco-Free Oral Nicotine Pouches that are capable of causing any allergies or intolerances in a limited sub-group of the population on the outer packaging.

To further ensure safety to the users, allergic substances and constituents that may be present in the finished product shall be clearly stated on the outer packaging to inform

consumers/users of potential intolerances to the Consumable. Table 2 depicts such common/typical allergens.

Table 2. Potential allergens/sensitizers

Allergenic substance or product	Exceptions
Gluten, obtained from cereals, particularly wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof	• Wheat based glucose syrups including dextrose, and products thereof • Wheat based maltodextrins, and products thereof • Glucose syrups based on barley • Cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin
Crustaceans and products thereof	
Eggs and products thereof	
Fish and products thereof	• Fish gelatin
Peanuts and products thereof	
Soybeans and products thereof	• Fully refined soybean oil and fat, and products thereof • Natural mixed tocopherols, natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources • Vegetable oils derived phytosterols and phytosterol esters from soybean sources • Plant stanol ester produced from vegetable oil sterols from soybean sources
Milk and products thereof (including lactose)	• Whey used for making alcoholic distillates including ethyl alcohol of agricultural origin • Lactitol
Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof	• Nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin
Celery and products thereof	
Mustard and products thereof	
Sesame seeds and products thereof	
Lupin and products thereof	
Molluscs and products thereof	

5.7. Supply Chain Requirements

All consumable ingredients shall be supplied with a unique, appropriate batch code.

All consumable ingredients shall be accompanied by the certificate of analysis and/or conformity demonstrating compliance with the purity requirements.

6. REQUIREMENTS FOR THE FINAL PRODUCT

6.1. Product Naming

The product name shall be unique, non-promotional and not appealing to individuals under 18 years of age.

6.2. Nicotine Limit

Products with extremely high doses of nicotine pose an increased level of potential risk to the user, as well as to non-nicotine users (especially young children) via accidental exposures. This requires risk-mitigation. Therefore, a proposal of nicotine quality and level should be enforced.

The limit of nicotine per pouch is recommended to be a maximum of 20mg per consumable. If nicotine compounds other than nicotine are added to the product, the 20mg per consumable limit applies to the nicotine part of the nicotine compound.

An analytical method that could be used to measure the nicotine content can be based on the CORESTA Recommended Method No 87 or CORESTA Recommended Method No 86, or equivalent validated and independently accredited methods or published peer-reviewed methods.

7. REQUIREMENTS FOR PACKAGING

The seal of the Consumable packaging shall be tamper evident such that a user can visually discriminate whether the product has been opened since the manufacture.

8. PRODUCT INFORMATION AND LABELLING

Packaging and labelling of Tobacco-Free Nicotine-Containing Oral Pouches shall comply with the appropriate local regulatory requirements.

8.1. Physical requirements:

Unit packet of Tobacco-Free Nicotine-Free Oral Pouches shall have a tamper proof seal to ensure the consumer that the contents have not been opened since manufacture.

Unless alternative child-safety text is mandated by local legislation, any potential outer packaging in which the product is sold to Consumers, as well as the product label and product information, shall carry the statement: “Keep Out of Reach of Children”

Appropriate Warning Statements including the addictive properties of nicotine i.e. a mandatory clear warning statement “*This product contains nicotine and is addictive*”, which should be located/printed on the side of the package.

Precautionary statements including “Keep out of reach of children” and “Not for sale to persons under the age of 18”

Company Name including address and Emergency Phone Number (Poisons Center), which should be furnished with details of the ingredients used in the product once the product is launched into the relevant market.

The packaging and labelling clearly advise users to dispose of the product responsibly.

Nicotine strength should be included on the packaging of Tobacco-Free Nicotine-Containing Oral Pouches to inform users the concentration of nicotine in one consumable/pouch.

Net Weight depicting the individual weight and total weight of the pouches in the package.

Products shall carry a manufacturing and/or “best before” date or an expiry date. The information should be indelibly printed on the unit pack.

Storage conditions should be included on the packaging to ensure correct stability of the ingredients and avoid any untoward/adverse effects of the product.

All consumable ingredients shall be accompanied by appropriate relevant certificates of analysis demonstrating compliance with purity requirement.

8.2. Traceability

Each manufacturer has the responsibility to ensure the traceability of their product:

Traceability is a fundamental requirement for consumers, the enforcing authorities (Government) and the manufacturers. Traceability of tobacco-free nicotine oral products is mandatory, and the technology solution should comprise of the following key elements:

• Authentication – covert or overt that enable customers and law enforcement to verify the authenticity of our products

• Traceability – ability for law enforcement to trace the source of products and for consumers to determine where to purchase the product from legitimate retail locations

• Tamper resistance – product safety standards that prevent inadvertent issues and non-genuine components/ingredients from being introduced and consumed using devices

All Tobacco-Free Nicotine-Containing Oral Pouches manufactured in or imported into Kenya must ensure clear traceability mechanisms.

'Know your customer' controls with suppliers: Suppliers of key inputs must ensure the integrity of their materials as well as their supply chains. On request, these should be readily available to enforcing authorities.

All Tobacco-Free Nicotine-Containing Oral Pouches should be clearly sealed with an overt identifier clearly indicating that this product has not been tampered with and is considered safe to use as directed by the manufacturer.

An appropriate coding system (QR Code) should be implemented on all tobacco-free nicotine oral products detailing that this product is from the specific manufacturer and details thereof.

PS: 5468-2020

PAKISTAN STANDARD SPECIFICATION FOR

NICOTINE-CONTAINING TOBACCO FREE ORAL PRODUCT 3-(1- methyl, 2- Pyrrodinyl) Pyrindine

PAKISTAN STANDARDS AND QUALITY CONTROL AUTHORITY
STANDARDS DEVELOPMENT CENTRE, STANDARDIZATION WING
1ST FLOOR, ST-7-A, BLOCK-3, GULISTAN-E-JOHER, Karachi

PAKISTAN STANDARD SPECIFICATION
FOR
NICOTINE-CONTAINING TOBACCO FREE ORAL PRODUCT
3-(1- methyl, 2- Pyrrodinyl) Pyrindine

0. FOREWORD

0.1 This Pakistan Standard was adopted by the Pakistan Standard and Quality Control Authority on **19-August-2020** after the draft finalized by the Fine Chemical Technical Committee had been approved by the National Standard Committee for Chemical.

0.2 The Technical Committee responsible for preparation of this Standard and felt that it should be related to manufacturing trade and technological procedure followed in the country in this field.

0.3 For the purpose of deciding weather for particular requirement of this standard is compiled with the final value observed or calculated, expressing the result of test or analysis shall be rounded off in accordance with "method of rounding of numerical values PS: 103-1991. The number significant places related in the rounded off values should be the same as that of the specified value in this standard.

0.4 This Standard is intended to cover the technical chiefly to cover the technical provision relating to the material and it does not include the necessary provision of a contract

0.5 Nicotine-Containing, Tobacco-Free Oral Products are a distinct product category, requiring the establishment of robust product standards, to provide requirements governing the safety and quality of these products.

The purpose of this Standard is to define safety and quality related technical requirements for Producers. Meeting these requirements should reassure regulators and the public that product safety and quality is maintained across products and batches and can be reliably demonstrated with documentary evidence, and that appropriate information is provided and/or available to Consumers.

1. SCOPE

This Pakistan standard gives guidance on ingredient requirements, nicotine limits, product information and labeling and product certification requirements for Tobacco-Free, Nicotine Containing Oral Products exclusively intended for oral use, where the recommended method of consumption results in uptake of the nicotine via the oral mucosa.

NOTE: This includes products such as white pouched nicotine products that are used by placing them under the upper lip for a period of time, before disposal

This document is not intended to cover Nicotine-Containing, Tobacco-Free Oral Products that are licensed as medicinal products or medical devices, or that are governed by other product specific regulations.

2. NORMATIVE REFERENCES

The following document is referred to in the text in such a way that some or all of its content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Globally Harmonized System of Classification and Labeling of Chemicals (GHS), United Nations

3. DEFINITIONS AND ABBREVIATIONS

For the purposes of this document, the following definitions and abbreviations apply.

3.1 **Definitions**

3.1.1 Constituent

An individual chemical substance within an Ingredient

3.1.2 **Consumable**

A single portion of the Nicotine-Containing, Tobacco-Free Oral Product that is placed in the mouth for oral use

3.1.3 **Contaminant**

Unwanted and unintended substance or material

3.1.4 **Flavouring**

A chemical substance, extract or natural Ingredient that imparts a taste flavour or aroma to Nicotine-Containing, Tobacco-Free Oral Products

3.1.5 **Ingredient**

Any compound or mixture of compounds intentionally included in a Nicotine-Containing, Tobacco- Free Oral Product

Examples: cellulose, Nicotine, Flavourings

3.1.6 **Nicotine-Containing, Tobacco-Free Oral Product**

A portioned, chemical mixture including Nicotine, a solid substrate and potentially other additives such as Flavourings, but which does not contain tobacco, exclusively intended for oral use, where the recommended method of consumption results in uptake of the nicotine via the oral mucosa. The portioning of the chemical mixture may be achieved, for example by being in tablet form or contained within a pre-portioned single-use pouch.

3.1.7 **Nicotine**

The chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine.

3.1.8 **Producer**

The entity legally responsible for the Nicotine-Containing, Tobacco-Free Oral Product as supplied to a consumer.

4. REQUIREMENTS FOR INGREDIENTS

4.1 **Disclosure of Consumable / Flavouring formulation**

The Producer shall ensure they receive disclosure of all Ingredients used in the final Nicotine-Containing, Tobacco-Free Oral Product to a sufficient level of detail for assessment of the final product, including of any Flavouring pre-mixes that may be used in its production. Disclosure information is pivotal for toxicological risk assessment and control over potential Constituents of concern

The disclosure shall consist of the list of individual Ingredients, including their use level. Where the Ingredients are individual compounds, there shall be sufficient information to unambiguously identify the specific chemical entity, including stereochemistry information where applicable.

Where Ingredients consist of extracts of natural raw materials, disclosure information shall include the presence and maximum levels of any toxicologically undesirable Constituents

4.2 **Supply Chain Requirements**

All Consumable Ingredients shall be supplied with a unique batch code

All Consumable Ingredients shall be accompanied by the relevant certificates of analysis and/or

certificate of conformity demonstrating compliance with the purity requirement

NOTE To ensure sufficient quality in the supply chain, it is recommended to use Ingredient suppliers accredited for food flavour or pharmaceutical Ingredient production.

4.3 **EXCLUDED INGREDIENTS**

The Consumable shall not contain any ingredients or materials of animal-origin.

Alcohol (chemical name: ethanol,) shall not be present as an ingredient. If ethanol is used as a processing aid during production, this should be removed from the final product such that total residue levels in the final product are less than 0.5%.

TABLE 1
Toxicologically Undesirable Constituents That Can Be Naturally Present In Flavourings

Substance name
Beta-asarone
1-Allyl-4-methoxybenzene, also known as Estragole
Hydrocyanic acid
Menthofuran
4-Allyl-1,2-dimethoxy-benzene, also known as Methyleugenol
Pulegone
Quassin
1-Allyl-3,4-methylene dioxy benzene, safrole
Teucrin A
Thujone (alpha and beta)
Coumarin

4.4 The Nicotine used shall meet appropriate pharmaceutical standards, specified below. All other Ingredients used in the Consumable shall be of a purity that would also be appropriate for use with food.

Nicotine shall meet appropriate pharmaceutical grade purity requirements, such as the requirements specified in the European Pharmacopoeia, Nicotine Monograph (1452), or the United States Pharmacopeia, Nicotine Monograph (i.e. shall be EP or USP grade), with supporting documentation including certificate(s) of analysis and/or certificate(s) of conformity. If Nicotine salts are used as either an ingoing Ingredient, or formed in situ, the Nicotine used to form the Nicotine salts shall be of the before mentioned pharmaceutical grade quality and the acid added shall be equivalent to, or of better quality than, European or US food grade quality, with supporting documentation including certificate(s) of analysis and/or certificate(s) of conformity.

Although Nicotine-Containing, Tobacco-Free Oral Products are not ingested and not intended to be a food, to ensure appropriateness for the oral exposure route, all Flavourings, whether natural or artificial, shall be listed as Flavouring agents allowed in foods by appropriate regulatory authorities and/or assessed by expert bodies as Generally Recognized as Safe (GRAS) in foods. This would include Flavouring agents listed on at least one of the following lists

4.5 Undesirable Constituents

Where the toxicologically undesirable Constituents that can be naturally present in Flavourings, listed in Table 1 enter the product as Constituents of natural flavours, the presence of those undesirable Constituents in the final Consumable shall be restricted to levels deemed supportable

by the toxicological risk assessment. This can be done through controlling their limited presence in natural Flavourings and/or by limiting the inclusion level of natural Flavourings containing undesirable Constituents in the Consumable**.**

5. REQUIREMENTS FOR THE FINAL PRODUCT

5.1 Product Name

The product and flavour name shall be factual, non-promotional and not appealing particularly to children.

5.2 Nicotine limit

The maximum amount of Nicotine per Consumable shall be 20 mg.

An analytical method that could be used to measure the Nicotine content of the

Consumable is provided in Annex A.

6. REQUIREMENTS FOR PACKAGING

The seal of the Consumable packaging shall be tamper evident such that a user can visually discriminate whether the product has been opened since manufacture**.**

7. PRODUCT INFORMATION AND LABELLING

7.1 Warning

Consumer packaging and labeling of Nicotine-Containing, Tobacco-Free Oral Products shall be in accordance with applicable local regulatory requirements.

Where no alternative Nicotine addiction warning is prescribed by local legislation, products shall carry a clear and visible general health warning about the addictiveness of Nicotine:

“This product contains nicotine and is addictive”

The required warning statement shall be indelibly imprinted directly on the package and shall be clearly visible underneath any cellophane or other clear wrapping. In addition, the required warning statement shall:

- be located in a conspicuous and prominent place on one side panel of the external package, and
- appear in conspicuous and legible type that contrasts by typography, layout, or colour with all other printed material on the package.

Additionally, product labelling shall include a contact telephone number for feedback on products, including complaints and adverse events.

7.2 Child Safety

Unless alternative child-safety text is mandated by local legislation, any potential outer packaging in which the product is sold to Consumers, as well as the product label and product information, shall carry the statement.

“Keep out of reach of children”

7.3 Durability

Products shall carry a manufacturing or “best before” date.

7.4 Allergens and Contact Sensitisers

Table 2 contains substances or products that are capable of causing food allergies or intolerances in a limited sub-group of the population. If any Ingredients or processing aids are used in the manufacture or preparation of the oral tobacco-free Nicotine product, that contain, or are derived from the allergenic substances or products listed in table 2, and are still present in the finished product, even if in an altered form, the allergenic substance or product shall be clearly stated on the outer packaging in which the Consumables are sold to Consumers, as well as the product label and product information.

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TABLE 2
Food Allergens

Allergenic substance or product	Exceptions
Gluten, obtained from cereals, particularly wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof	• Wheat based glucose syrups including dextrose, and products thereof; • Wheat based maltodextrins, and products thereof; • Glucose syrups based on barley; • Cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin
Crustaceans and products thereof	
Eggs and products thereof	
Fish and products thereof	• Fish gelatin
Peanuts and products thereof	
Soybeans and products thereof	• Fully refined soybean oil and fat, and products thereof • Natural mixed tocopherols, natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources • Vegetable oils derived phytosterols and phytosterol esters from soybean sources • Plant stanol ester produced from vegetable oil sterols from soybean sources
Milk and products thereof (including lactose)	• Whey used for making alcoholic distillates including ethyl alcohol of agricultural origin • Lactitol
Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews	• Nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin

Allergenic substance or product	Exceptions
(Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof	
Celery and products thereof	
Mustard and products thereof	
Sesame seeds and products thereof	
Lupin and products thereof	
Molluscs and products thereof	

8. PRODUCT CERTIFICATION

If all the requirements in this standard are met, the Producer may self-certify confirming that to be the case. Any such certificate must specify the unique product descriptor(s) by which the Consumer will be able to recognise the product(s). This would generally be expected to be the brand and product variant, including any indications of flavour and/or Nicotine strength. Multiple products can be named in a single certificate, provided each meet the requirements described.

ANNEX A
(Informative)
Analytical method to measure Nicotine in Nicotine-Containing, Tobacco-Free Oral Products

A.1 SCOPE

This specifies methods for the determination of Nicotine level in a Nicotine-Containing, Tobacco- Free Oral Product. The method is applicable to any type of sample whose particle size has been reduced to totally pass through a 4 mm screen.

A.2 TERMS, ABBREVIATIONS, DEFINITIONS

MTBE: methyl tertiary-butyl ether

GC: gas chromatographic

FID: flame ionization detection

SST: System Suitability

A.3 PRINCIPLE

This method is based on CORESTA Recommended Method No. 62, following the gas-chromatographic procedure using MTBE as a solvent or, alternatively, hexane as a solvent [1].

The Nicotine content of a sample of a Nicotine-Containing, Tobacco-Free Oral Product is determined by liquid/liquid extraction into an organic extraction solvent containing an internal standard, followed by gas chromatographic (GC) analysis with flame ionization detection (FID).

A.4 REAGENTS

Use only reagents of recognized analytical grade. Reagents specific to each analytical approach are identified as either (MTBE method) or (Hexane method).

A.5 APPARATUS

Normal laboratory apparatus and the following items:

Volumetric flasks of capacities 50 ml, 2000 ml, 3000 ml etc.

Extraction vessels (250 ml Erlenmeyer flasks with stoppers and 100 ml for hexane method) and clamps

Automatic pipet with positive displacement

Mettler Toledo balance (four digits)

Dispensers

Orbital shaker (200 rpm or more)

Capillary gas chromatograph (GC), equipped with a flame ionization detector, a split inlet system, and a data station or integrator for data collection.

GC column for MTBE method: DB-5MS ultra inert, 30 m, 0,32 mm ID, 0,25µm

GC column for hexane method: DB-WAX ultra inert, 15 m, 0,53 mm ID, 1µm GC liner:

Split ultra-inert liner

A.6 GAS CHROMATOGRAPHY - OPERATING CONDITIONS

MTBE method:

Carrier gas: nitrogen or helium

Injection mode: split (30:1)

Injection volume: 1 µl

Column flow rate: 1,7 ml/min (constant pressure mode)

Temperatures:

- Inlet 270°C
- Detector 270°C
- Oven
    - Initial 110°C, hold time 0 min
    - Gradient 6° C/min to 160° C, hold time 0 min, 30° C/min till 250° C
    - Final 250°C, hold time 10min

Total analysis time: 21.33 min

Hexane method:

Carrier gas: nitrogen or helium

Injection mode: split (10:1)

Injection volume: 1 µl

Column flow rate: 5 – 6 ml/min

Temperatures:

- Inlet 270°C
- Detector 270°C
- Oven 170°C

Total analysis time: 10 min

A.7 PREPARATION OF EXTRACTION SOLUTION AND STANDARDS

Prepare a series of at least five Nicotine standard solutions whose concentrations cover the range expected to be found in the test portion. For example.

Nicotine stock solution (5 mg/ml)

Weigh 0.5000 g of Nicotine base (III) in a 250 ml Erlenmeyer flask and dissolve in 50 ml of water. Subsequently add 100 ml of the extraction solution and 25 ml of sodium hydroxide solution (V). Shake the two-phase mixture obtained vigorously for 60 ± 2 min using a shaker. Care should be taken to mix the phases well. Subsequently separate the supernatant organic phase and store the stock solution obtained in a dark glass bottle at 4°C to 8°C

Nicotine standards		
Standard	**Nicotine stock (ml)**	**Extraction solution up to**
S1 (0.1 mg/ml)	1	50 ml
S2 (0.2 mg/ml)	2	50 ml
S3 (0.4 mg/ml)	4	50 ml
S4 (0.6 mg/ml)	6	50 ml
S5 (0.8 mg/ml)	8	50 ml

If the samples should have a Nicotine content below S1 (used snus pouches) a lower standard (S0) must be prepared.

Standard	**Nicotine stock (ml)**	**Extraction solution up to**
S0 (0.05 mg/ml)	0.5	50 ml

MTBE method

Extraction solution with internal standard (0.4 mg/ml)	
Quinaldine (IV)	0.4000 g
Methyl tertbuthyl ether (II) up to	1 liter

The extraction solution and standard solutions shall be made up fresh each analysis time. Quinaldine is light and air sensitive and therefore the standard solutions shall be treated in the same manner as the samples, namely shaken with 7 ml NaOH in Erlenmayer flasks for 2 hours.

Hexane method

Extraction solution with internal standard (0.4 mg/ml)	
Heptadecane (VII)	0.5000 g
Hexane (VI) up to	1 liter

A.8 SAMPLE PREPARATION

Always prepare two replicates of each test samples.

MTBE method

Depending on the expected Nicotine content, 1±0.4 g of test sample is weighed to 0,0001 g accuracy into a 250 ml Erlenmeyer flask.

Consumables shall be cut in two and analysed "as is" [2]

Pipette 7 ml of 5N NaOH into the flasks using a non-glass 10 ml volumetric dispenser, swirl to wet sample and allow to stand 15 minutes.

Pipette 50,0 ml of extraction solution into the flasks using a 50 ml volumetric dispenser.
Place flasks on the shaker and shake for two hours. Remove flasks from shaker and allow the phases to separate for 15-30 min. Transfer aliquot from extraction flask to a GC vial and cap.

Hexane method

Depending on the expected Nicotine content, 1±0.4 g of test sample is weighed to 0,0001 g accuracy into a 100 ml Erlenmeyer flask.

Consumables shall be cut in two and analysed "as is" [2].

Pipette 20 ml of water into the flasks using a 50 ml volumetric dispenser.

Pipette 40,0 ml of extraction solution into the flasks using a 50 ml volumetric dispenser.

Pipette 10 ml of 8N NaOH into the flasks using a non-glass 10 ml volumetric dispenser.

Place flasks on the shaker and shake for two hours. Remove flasks from shaker and allow the phases to separate for 15-30 min. Transfer aliquot from extraction flask to a GC vial and cap.

A9. GC ANALYSIS

Set up and operate the gas chromatograph, data station or integrator and autosampler (if used) according to the manufacturer's instructions. Ensure that the peaks for solvent, internal standard, and Nicotine are well resolved. Condition the system just prior to use by injecting two 1,0 µl aliquots of a sample solution or a Nicotine standard as a primer.

Optimize the GC conditions for analyte separation and sensitivity. Once optimized, the same GC conditions must be used for the analysis of all standards and samples, including the same injection volume of 1,0 µl.

Calibration of the gas chromatograph

Follow the manufacturer's instructions for calibrating the GC.

A typical procedure would be to inject an aliquot of each of the Nicotine standards into the gas chromatograph. Record the peak areas (or height) of Nicotine and the internal standard. Carry out the determination at least twice, with one series interspersed with the test portion injections.

Calculate the ratio of the Nicotine peak to the internal standard peak ($Y = A_{Nicotine}/A_{IS}$) from the peak area (or height) data for each of the Nicotine standards including the solvent blanks. Plot the graph of the concentrations of added Nicotine (X axis) in accordance with the area ratios (Y axis). Calculate a linear regression equation ($Y = a + bx$) from this data, and use both the slope (b) and the intercept (a) of the linear regression.

If the correlation coefficient R^2 is less than 0,99, then the calibration should be repeated. If an individual calibration point differs by 10 % or more from the expected value (estimated by linear regression), it should be omitted. The signal (peak area or height) obtained for all test portions must fall within the working range of the calibration curve.

A.10 DETERMINATION OF THE NICOTINE CONTENT OF SAMPLES

Inject replicate aliquots of the test portion from the sample extracts. A minimum of two replicate determinations should be made under identical conditions.

Calculate the test portion ratio of the Nicotine response/internal standard response (Y_t) from the peak area (or height) data. Calculate the mass of Nicotine for each test portion aliquot using the coefficients of the linear regression ($m_t = (Y_t - a)/b$)

The Nicotine content, m_n , of the test sample expressed in milligrams per gram, is given by the equation

$$m_n = m_t / m_0$$

where m_t is the mass of Nicotine in the test portion in mg; m_0 is the mass of the test portion (dry weight), in g.

A.11 SPECIAL PRECAUTIONS

It is beneficial to purge high boiling point components from the column in between each large sample set. Typically, raising the temperature to 220 °C, for 30 minutes has been found to be sufficient.

Recondition the chromatographic column when the instrument has been used infrequently and after replacing the glass liner.

Glass liner and septum should be replaced if method requirements are not fulfilled or the chromatography is poor (variation in retention times, unexpected peeks, unstable baseline, etc.)

When analyzing new non-tobacco, Nicotine products, extract product without IS to determine if any components co-elute with the IS. This interference could artificially lower the calculated values for Nicotine.3

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Teknisk specifikation
SIS/TS 72:2020

Nikotininnehållande, tobaksfria orala produkter – Säkerhets- och kvalitetsrelaterade krav

Nicotine-containing, tobacco-free oral products – Safety and quality related requirements

Swedish Institute for Standards

Språk: engelska/English

Utgåva: 1

Swedish Institute for Standards

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Fastställd: 2020-09-17
ICS: 65.160

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Introduction

This document was prepared by Technical Committee SIS/TK 442 Tobacco at the Swedish Institute for Standards, SIS. This document is intended to ensure product and consumer safety requirements for nicotine-containing, tobacco-free, oral products.

The purpose of this document is to define safety and quality related requirements for producers of nicotine-containing, tobacco-free, oral products. Meeting these requirements intends to reassure regulators and the public that product safety and quality is maintained across products and batches and can be reliably demonstrated with documentary evidence, and that appropriate information is provided and/or available to consumers.

1 Scope

This document establishes limits for nicotine content and pH, and specifies requirements for ingredients and materials, and product information and labelling for nicotine-containing, tobacco-free oral products not intended for medicinal use.

This document is applicable to pre-portioned, nicotine-containing, tobacco-free oral products exclusively intended for oral use, and for uptake of the nicotine via the oral mucosa.

NOTE This includes products such as white pouched nicotine products that are used by placing them under the upper lip for a period of time, before disposal.

This document also gives guidelines for analytical methods for measuring nicotine content and pH, as well as certain aspects of toxicological risk assessments.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Globally Harmonized System of Classification and Labelling of Chemicals (GHS), United Nations

European Pharmacopoeia, Nicotine Monograph (1452)

United States Pharmacopeia, Nicotine Monograph

CORESTA Recommended Method No. 69 (Determination of pH of Tobacco and Tobacco Products)

IARC Monographs on the Identification of Carcinogenic Hazards to Humans (https://monographs.iarc.fr/list-of-classifications/)

NTP Report on Carcinogens (https://ntp.niehs.nih.gov/go/roc)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
nicotine-containing, tobacco-free oral product
sv. nikotininnehållande tobaksfri oral produkt
pre-portioned, product that contains *nicotine* (3.5) compounds and typically *flavourings* (3.6) and other *ingredients* (3.3), but which does not contain tobacco, exclusively intended for oral use, and for uptake of the *nicotine* (3.5) via the oral mucosa

Note 1 to entry: The term pre-portioned means that the product comes in portion form, namely forms such as sachets, pouches and other similar forms, specifically designed to facilitate the oral function or application of the nicotine-containing, tobacco-free oral product in measured small unit quantities.

3.2
consumable
sv. portion
single portion of a *nicotine-containing, tobacco-free oral product* (3.1) that is placed in the mouth for oral use

3.3
ingredient
sv. ingrediens
substance (individual chemically defined substance or consisting of a mixture of substances) added to make the *nicotine-containing, tobacco-free oral product* (3.1)

EXAMPLE cellulose, *nicotine* (3.5), *flavouring* (3.6)

3.4
constituent
sv. beståndsdel
individual chemically defined substance within an *ingredient* (3.3)

3.5
nicotine
sv. nikotin
the chemical substance named 3-(1-methyl-2-pyrrolidinyl) pyridine

3.6
flavouring
sv. arom
ingredient (3.3) that imparts smell and/or taste to *nicotine-containing, tobacco-free oral products* (3.1)

3.7
unit packet
sv. styckförpackning
smallest individual packaging of a *nicotine-containing, tobacco-free oral product* (3.1) that is placed on the market

EXAMPLE A can.

3.8
outside packaging
sv. ytterförpackning
packaging in which *nicotine-containing, tobacco-free oral products* (3.1) are placed on the market and which includes a *unit packet* (3.7) or an aggregation of *unit packets* (3.7)

Note 1 to entry: Transparent wrappers are not regarded as outside packaging.

3.9
producer
sv. tillverkare
natural or legal person who manufactures a *nicotine-containing, tobacco-free oral product* (3.1), or has a *nicotine-containing, tobacco-free oral product* (3.1) designed or manufactured and markets that product under their name or trademark

4 Abbreviated terms

The following abbreviated terms are used in this document.

CAS	Chemical Abstracts Service registration number

CoE number	number of a material listed in the Council of Europe's reports on chemically defined flavouring substances and natural sources of flavourings
EP	European Pharmacopoeia
FEMA	Flavor and Extract Manufacturers Association of the United States
FL-number	European Union flavouring information system (FLAVIS) number
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GRAS	Generally Recognised as Safe
JECFA	Joint FAO/WHO Expert Committee on Food Additives
USP	United States Pharmacopeia

5 Requirements for ingredients

5.1 Disclosure of consumable / flavouring formulation

The producer shall ensure that its suppliers disclose to the producer all necessary information about the ingredients to facilitate safety assessment of the final nicotine-containing, tobacco-free oral product, including of any flavouring pre-mixes that can be used in its production. The disclosure information shall consist of a full list of ingredients, including their use level, and, if available, identification numbers such as CAS, FEMA, JECFA, CoE and/or FL-numbers.

5.2 Supply chain requirements

All ingredients shall be supplied with a unique batch code.

To ensure sufficient quality in the supply chain, it is recommended to use ingredient suppliers active in food or pharmaceutical ingredient production.

5.3 Excluded ingredients

5.3.1 Ingredients shall not be used in the manufacture of any nicotine-containing, tobacco-free oral product if they meet any of the following classification criteria of the GHS via the oral route of exposure:

— carcinogenicity (category 1 or 2);

— germ cell mutagenicity (category 1, 1A, 1B or 2);

— toxic to reproduction (category 1, 1A or 1B, or effects on or via lactation).

5.3.2 In addition, ingredients shall not be used in the manufacture of any nicotine-containing, tobacco-free oral product if they have been identified as any of the following:

— classified as “Carcinogenic to humans” (Group 1), “Probably carcinogenic to humans” (Group 2a) or “Possibly carcinogenic to humans” (Group 2b) by the International Agency for Research on Cancer (IARC);

— identified by the United States National Toxicology Program (NTP) as either “Known” or “Reasonably Anticipated To Be” human carcinogens.

5.3.3 The only exception to 5.3.2 is if scientific data has become available after the evaluation that resulted in the inclusion of the compound in one, or more, of the lists mentioned in 5.3.2, given that the weight of evidence shows that the specified toxicological end point is not relevant to humans for the anticipated exposure level(s) and route(s). In that case the ingredient may be used

but the documented toxicological risk assessment (according to 5.6) determining the supportable concentration in the consumable shall include a scientific justification for its use despite its presence on one, or both, of the lists in 5.3.2.

5.3.4 Certain toxicologically undesirable constituents can be naturally present in flavourings. Those listed in Table 1 shall not be used as ingredients in their own right, but can be present as constituents of ingredients (see 5.5).

Table 1 — Toxicologically undesirable constituents that can be naturally present in flavourings

Substance name	CAS number(s)
agaric acid	666-99-9
aloin	1415-73-2
capsaicin	404-86-4
hypericine	548-04-9
beta-asarone	5273-86-9
1-allyl-4-methoxybenzene, also known as estragole	140-67-0
hydrocyanic acid	3017-23-0
menthofuran	494-90-6
4-allyl-1,2-dimethoxy-benzene, also known as methyleugenol	93-15-2
pulegone	89-82-7; 15932-80-6
quassin	76-78-8
1-allyl-3,4-methylenedioxybenzene, also known as safrole	94-59-7
teucrin A	12798-51-5
thujone (alpha and beta)	546-80-5; 76231-76-0
1,2-benzopyrone, also known as coumarin	91-64-5

5.4 Ingredient quality

The nicotine used shall meet the requirements of appropriate pharmaceutical standards, specified below. All other ingredients used in the consumable shall be of food or pharma grade quality.

Nicotine shall meet appropriate pharmaceutical grade purity requirements, such as the requirements specified in the European Pharmacopoeia, Nicotine Monograph (1452), or the United States Pharmacopeia, Nicotine Monograph, i.e. shall adhere to EP or USP specifications, with supporting documentation including certificate(s) of analysis and/or certificate(s) of conformity. If nicotine salts are used as either an ingoing ingredient, or formed in situ, the nicotine used to form the nicotine salts shall be of the before mentioned pharmaceutical grade quality and the acid added shall be equivalent to, or of better quality than, European or US food grade quality, with supporting documentation including certificate(s) of analysis and/or certificate(s) of conformity.

Although the consumables are not ingested and not intended to be a food, to ensure appropriateness for the oral exposure route, all flavourings, whether natural or artificial, and all additives, which are governed by the European flavourings or food additives regulations, shall be restricted to substances allowed in foods by appropriate regulatory authorities and/or assessed by

expert bodies as Generally Recognized as Safe (GRAS) in foods. This includes substances listed on at least one of the following lists:

— Annex 1 of European Flavourings Regulation EC 1334/2008 (regarding flavourings), or European Food Additives Regulation EC 1333/2008 (regarding additives);

— FDA's Substances Added to Food Inventory of the United States;

— FEMA GRAS listings;

— International Organization of the Flavor Industry (IOFI) Global Reference List of Natural Complex Substances / Natural Flavouring Complexes (regarding flavourings);

— Council of Europe's reports on chemically defined flavouring substances and natural sources of flavourings.

NOTE The European Union list of Flavouring substances can also be consulted in the form of the Food Flavourings Database.

5.5 Undesirable constituents

Toxicologically undesirable constituents, from all ingredients, with particular reference to those listed in Table 1, in the final consumable shall be restricted to levels deemed supportable by the toxicological risk assessment according to 5.6.

5.6 Toxicological risk assessment

The producer shall ensure that the use of the ingredients in a final consumable is or has been subject to a toxicological risk assessment, demonstrating safety under reasonable and foreseeable use. The toxicological risk assessment itself, or a summary thereof, shall be documented by the producer for each commercial product. Product changes and/or availability of critical new information/data on ingredients require an updated toxicological risk assessment.

In order to determine the supportable level of ingredient use, the toxicological risk assessment shall assess the potential hazards associated with the ingredients and, where applicable, those of any undesirable constituents (see 5.5), as well as the expected exposure to the consumer. The expected exposure shall be based on reasonable and foreseeable use of the product.

NOTE Detailed guidance on consumer toxicological risk assessments, estimating consumer exposures and the use of appropriate safety factors in risk assessment can be found, amongst others, in the guidance supporting the European chemicals regulation [ECHA, 2018]. These same principles are described in the risk assessment approach recommended by the Research Institute for Fragrance Materials [RIFM, 2015].

Toxicological risk assessments ultimately rely on expert judgements of competent risk assessors in interpreting the different data sources. Appropriately competent individuals and procedures shall therefore be involved in the toxicological risk assessment.

6 Requirements for the final product

6.1 Nicotine limit

The maximum total amount of nicotine per consumable shall be 20 mg.

If nicotine compounds other than nicotine is added to the product, the 20 mg per consumable limit applies to the nicotine part of the nicotine compound.

NOTE The analytical method to measure the nicotine content of the consumable can be based on the CORESTA Recommended Method No. 87 (Determination of Nicotine in Tobacco Products by GC/MS) or CORESTA Recommended Method No. 62 (Determination of Nicotine in Tobacco and Tobacco Products by Gas Chromatographic Analysis), or equivalent published peer-reviewed methods, or equivalent validated and independently accredited methods.

Method repeatability and reproducibility as established during method validation shall be taken into account during evaluation of analytical results.

6.2 pH limit

The maximum pH value of the consumable shall be 9,1, unless a risk assessment of the final product, that includes appropriate data and is documented in a toxicological risk assessment (see 5.6) supports the final product pH used.

The analytical method to measure the pH value of the consumable shall be based on the CORESTA Recommended Method No. 69 (Determination of pH of Tobacco and Tobacco Products), or the method described in Federal Register Vol. 74, No. 4, 712-719 (Revised Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products), or equivalent published peer-reviewed methods, or equivalent validated and independently accredited methods.

Method repeatability and reproducibility as established during method validation shall be taken into account during evaluation of analytical results.

6.3 Water activity

Water activity shall be evaluated during product stability studies. If water activity exceeds 0,7, an additional toxicological risk assessment (see 5.6) shall be conducted focusing on microbiological activity.

7 Requirements for material in unit packets etc

Unit packets, as well as any wrapping material (e.g. non-woven sachet) coming into contact with the ingredients, shall – although the consumables are not ingested and not intended to be a food – meet the requirements for composition and properties that apply for material and products intended to come into contact with foodstuffs, such as set out in the European Regulation (EC) No 1935/2004.

8 Product information and labelling

8.1 General

Unit packets and outside packaging, as applicable, which are targeting consumers shall meet the criteria specified in this clause.

NOTE There can also be additional national regulatory requirements.

8.2 Warning

8.2.1 Where no alternative nicotine addiction warning is prescribed by local legislation, outside packaging and unit packets shall carry a clear and visible general health warning about the addictiveness of nicotine, with the following wording:

“Denna produkt innehåller nikotin som är ett mycket beroendeframkallande ämne.”

NOTE This Swedish wording translates to: “This product contains nicotine which is a highly addictive substance.”

8.2.2 The required warning statement shall comply with the following technical labelling requirements:

— be located in a conspicuous and prominent place on one panel of the packaging;

— appear in conspicuous and legible type that contrasts by typography, layout, or colour with all other printed material on the package;

— not be obscured by any external wrapping.

8.3 Child safety

Where no alternative child-safety text is mandated by local legislation, outside packaging and unit packs shall carry information that the product is not for people under the age of 18, for example by using appropriate symbol(s) or having the following statements translated to Swedish:

— “Keep out of reach of children”;

— “Sale to persons under age 18 prohibited”.

The information shall comply with the technical labelling requirements set out in 8.2.2.

8.4 Ingredient list

Product labelling shall include a list of ingredients contained in the nicotine-containing, tobacco-free oral product in descending order of the weight. All ingredients with the main purpose of flavouring may be grouped together under the word ‘flavourings’ as translated into Swedish.

This information shall be indelibly printed on the unit pack and, unless this information on a unit pack is uncovered and hence fully visible, also on the outside packaging.

8.5 Nicotine content

Product labelling shall include information about the content of nicotine per consumable, expressed in mg/consumable. This information shall be indelibly printed on the unit pack and, unless this information on a unit pack is uncovered and hence fully visible, also on the outside packaging.

8.6 Durability

Products shall carry a manufacturing date and/or a “best before” or an expiry date.

This information shall be indelibly printed on the unit pack.

8.7 Batch number and information about manufacturer

Products shall carry a batch number indelibly printed on the unit pack.

Product labelling shall include the producer name and contact details for consumer questions, feedback and adverse event reporting, indelibly printed on the unit pack and, unless this information on a unit pack is uncovered and hence fully visible, also on the outside packaging.

8.8 Allergy

Table 2 contains substances or products that are capable of causing food allergies or intolerances in a limited sub-group of the population. If any ingredients or processing aids are used in the manufacture or preparation of the nicotine-containing, tobacco-free oral products, that contain, or are derived from the allergenic substances or products listed in Table 2, and are still present in the finished product, the allergenic substance or product shall be indelibly printed on the unit pack and, unless this information on a unit pack is uncovered, and hence fully visible, also on the outside packaging.

Table 2 — Substances or products that are capable of causing food allergies or intolerances

Allergenic substance or product	Exceptions
Gluten, obtained from cereals, particularly wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof	Wheat based glucose syrups including dextrose, and products thereof Wheat based maltodextrins, and products thereof Glucose syrups based on barley Cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin
Crustaceans and products thereof	
Eggs and products thereof	
Fish and products thereof	Fish gelatin
Peanuts and products thereof	
Soybeans and products thereof	Fully refined soybean oil and fat, and products thereof Natural mixed tocopherols, natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources Vegetable oils derived phytosterols and phytosterol esters from soybean sources Plant stanol ester produced from vegetable oil sterols from soybean sources
Milk and products thereof (including lactose)	Whey used for making alcoholic distillates including ethyl alcohol of agricultural origin Lactitol
Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof	Nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin
Celery and products thereof	
Mustard and products thereof	
Sesame seeds and products thereof	

Allergenic substance or product	Exceptions
Lupin and products thereof	
Molluscs and products thereof	

8.9 Contact sensitisers

The trivial name, if available or otherwise the chemical name, of any ingredients that meet the GHS and/or CLP classification criteria for contact sensitisation, and are present in the finished consumable at levels above 0,1 % (weight/weight) for category 1 and category 1B contact sensitisers, or 0,01 % for category 1A contact sensitisers, shall be indelibly printed as 'Contains "name of the sensitising substance"', as translated into Swedish, adjacent to the ingredient list.

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