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ICS 65.160

DRAFT EAST AFRICAN STANDARD

Nicotine pouches — Specification

EAST AFRICAN COMMUNITY

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Introduction

Tobacco-free oral nicotine pouches are a rapidly growing category of products in the world. It is therefore important to provide requirements governing their composition, safety and quality across the complete life cycle from manufacturer to consumer.

The purpose of this standard is to define safety and quality requirements for producers of nicotine pouches. Meeting these requirements intend to reassure regulators and the public that product safety and quality is maintained across products and batches and can be reliably demonstrated with documentary, and that appropriate information is provided and/or available to consumers.

Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

In order to achieve this objective, the Community established an East African Standards Committee mandated to develop and issue East African Standards.

The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the private sectors and consumer organizations. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the procedures of the Community.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 013, *Tobacco and tobacco products*.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

Nicotine pouches — Specification

1 Scope

This draft East African Standard prescribes the requirements, methods of test and sampling for pre-portioned nicotine pouches exclusively intended for oral use by placing them between the gum and buccal mucosa for a period, to facilitate uptake of the nicotine via the oral mucosa, followed by disposal of the pouch after use.

Note: this includes products such as white pouched nicotine products that are used by placing them under the upper lip for a period, before disposal.

This draft East African standard does not cover;

i. pre-portioned, tobacco-free oral nicotine pouches in which the nicotine is not of natural origin;

ii. smokeless tobacco products, such as moist snuff, tobacco oral pouches, snus, nasal snuff, chewing tobacco or any other tobacco-containing smokeless tobacco products;

iii. Nicotine-Containing, Tobacco-Free Oral Products that are licensed medicinal nicotine products, such as nicotine replacement therapies (NRT);

iv. products that are subject to an authorization requirement under Directive 2001/83/EC (Community code relating to medicinal products for human use) or to the requirements set out in Directive 93/42/EEC (Medical Device Directive) or

v. inhaled-nicotine products, such as cigarettes, other combusted tobacco products, tobacco-heating products or e-cigarettes.

vi. method for assessing the health risks or potential reduced health risks of tobacco-free oral nicotine pouches.

2 Normative references

The following referenced documents are indispensable for the application 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.

Codex Stan 192 General standard for food additives

ISO 15152 Tobacco and tobacco products-Determination of the content of total alkaloids as nicotine — Continuous-flow analysis method

ISO 15592-1 Fine-cut tobacco and smoking articles made from it — Methods of sampling, conditioning and analysis — Part 1: Sampling

ISO 18787- Foodstuffs — Determination of water activity

CORESTA Recommended Method No. 88 Determination of water activity of tobacco and tobacco products

CORESTA Recommended Method No. 69 Determination of pH of tobacco and tobacco products

3 Terms and definitions

For the purposes of this standard, the following terms and definitions shall apply

3.1 nicotine pouches
Pre-portioned, product that contain nicotine compound, typically flavorings and other ingredients, but which does not contain tobacco, exclusively intended for oral use and for uptake of the nicotine via the oral mucosa.
Note 1 to entry: The term pre-portioned means that product comes in portion form, namely forms such as in tablet form, sachets, pouches and other similar forms, specifically designed to facilitated the oral function or application of the nicotine pouches in measured small unit quantities.

3.2 ingredient
Substance (individual chemically defined substance or consisting of a mixture of substances) added to make the nicotine pouches. Example cellulose, nicotine, flavouring but exclude pouch materials.

3.3 consumable
Single portion of nicotine pouches that is placed in the mouth for oral use

3.4 nicotine compound
substance in which nicotine is chemically or physically associated with other chemical species
NOTE This includes (but is not limited to) nicotine salts, where the nicotine compound is produced by reaction of nicotine with a protonating species such as an acid functionality, and materials where nicotine is chemisorbed or physisorbed onto a substrate.

3.5 nicotine
The chemical substance named 3-[1-methyl-2-pyrrolidinyl] pyridine.

3.6 unit packet
the smallest individual packaging of the nicotine pouches that is placed on the market for sale.

3.7 flavouring
chemical substance, extract or natural Ingredient that imparts smell and/or taste or aroma to nicotine pouches.

3.8 outside packaging
Packaging (excluding transparent wrappers) in which nicotine pouches are placed on the market and which included a unit packet or an aggregation of unit packets.

3.9 batch
quantity of finished goods or intermediates of consistent quality produced at one time as defined by the manufacturer

3.10 component
functional element or part of a tobacco-free oral nicotine pouch
Note: Examples include ingredients andpouch materials.

3.11 constituent
individual chemical substance within an ingredient, material or product

3.12 manufacturer
person, company or legal entity that manufactures or designs a tobacco-free oral nicotine pouch product

3.13 packaging material
material comprising the container holding, and in contact with, the tobacco-free oral nicotine pouches

3.14 pouch material
porous material that forms the outer surface of a consumable enclosing the integrated composition of the product ingredients

3.15 tobacco
the tobacco plant, including its seeds and leaves

3.16 tobacco product

a product composed, in whole or in part, of tobacco, including tobacco leaves and any extract of tobacco leaves intended for use by smoking, inhalation, chewing, sniffing or sucking and includes cigarette papers, tubes and filters;

3.17 toxicological risk assessment (TRA)
process by which the toxicological risks to consumers associated with the use of tobacco-free oral nicotine pouches are evaluated and subsequently reviewed by a trained toxicologist.

3.18 Contact sensitizers
Substances that can cause allergic reactions or skin irritation.

4 REQUIREMENTS

4.1 General requirements
4.1.1 All ingredients used shall be safe, good quality (food or pharma grade quality) and supplied with a unique batch code.

4.1.2 The nicotine used shall meet the requirements of appropriate pharmaceutical standards

4.1.3 Pouch materials shall meet the requirements for material and products intended to come into contact with foodstuffs.

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

4.2 Ingredients
Nicotine and/or nicotine compounds

4.3 Specific requirements
Nicotine pouches shall conform to the requirement specified in the Table 1 when tested in accordance with the methods specified therein;

Table 1: Specific requirement for nicotine pouches.

S/N	CHARACTESTICS	REQUIREMENT	METHOD OF TEST
I	Water activity, max	0.7	CORESTA 88 or ISO 18787
II	Nicotine content, mg/pouch, (on dry basis) max	20	ISO 15152
III	pH, max	9.1	CORESTA 69

4.4 Harmful substances

4.4.1 The materials shall not contain any substances injurious to health as covered in respective tobacco control regulation and Act. Any added substance shall be of a nature and purity, which are suitable for use as food additive, medicinal, or pharmaceutical products in proportions of proved harmlessness.

4.4.2 Ingredients shall not be used in the manufacture of any nicotine pouches if they meet any of the following classification criteria of the GHS via oral route of exposure;

i. Carcinogenicity (category 1 or 2;
ii. Germ cell mutagenicity (category 1, 1A, 1B or 2)
iii. Toxic to reproduction (category 1, 1A, 1B, or effects on or via lactation)

Note: information on categories above may be found in Annex A

4.4.3 Ingredients shall not be used in the manufacture of any nicotine pouches if they have been identified as Classified as “Carcinogenic to humans” (Group 1), “probably carcinogenic to human” (Group 2a) or “Possibly carcinogenic to humans” (Group 2b) by the International Agency for Research on Cancer (IARC);

4.4.4 Certain toxicologically undesirable constituents can be found naturally present in the flavorings. Those listed in the Table 2 shall not be used as ingredients in their own right but can be present as constituents of ingredients.

Table 2: 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

4.5 Toxicological risk assessment

4.5.1 The manufacturer shall conduct a toxicological risk assessment (TRA) on all consumable components, their quantities present, and all packaging materials that are in contact with the consumables, in order to establish their suitability for use in the finished product.

4.5.2 To determine the toxicologically supportable level of material use, the TRA shall evaluate the potential hazards associated with the materials, including where applicable, those of any undesirable constituents. The TRA shall evaluate likely exposure to the consumer considering both duration and site of product use, based on reasonable and foreseeable use of the product.

4.5.3 The toxicological risk assessments shall be conducted either by a trained toxicologist, or under the supervision of a trained toxicologist, using established procedures. The completed risk assessment shall be reviewed by a trained toxicologist and documented by the manufacturer for each commercial product.

4.5.4 An updated toxicological risk assessment shall be conducted if the existing TRA is rendered obsolete by either:

i. changes to the product; or
ii. the availability of new ingredient hazard information/data.

5. Food additives

5.1 All flavorings whether natural or artificial and food additives used shall be restricted to substance allowed and or assessed by expert bodies as Generally Recognized as Safe (GRAS) in food and shall comply to Codex Stan 192.

5.2 Some 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 pouches, that contain, or are derived from the allergenic substances or products listed in Table 3, 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.

Table 3: 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 (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis (Wangenh.) K. Koch*), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia*	Nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin

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	

5.3 Contact sensitizers

Any ingredients or processing aids that meet the classification criteria for contact sensitization and are present in the finished consumable at the following levels shall be declared on the packaging as:

a) Category 1 contact sensitizer: above 0.1% (weight/weight); or

b) Category 1B contact sensitizer: above 0.1% (weight/weight); or

c) Category 1A contact sensitizer: above 0.01% (weight/weight).

6. Sampling

The method of representing samples of the material and the criteria for conformity shall be done as prescribed in *ISO 15592-1*

7. Packaging, marking and labelling.

7.1 Packaging.

7.1.1. The retail unit packet shall be packed using a suitable tight sealed packaging material to avoid contamination

7.1.2. Although the consumables are not ingested and are not a food, any wrapping material (including unit packet materials) coming into contact with the consumable shall meet requirements for materials and products intended to come into contact with foodstuffs.

7.1.3 The seal of the unit packet shall be tamper-evident such that a user can visually determine whether the product has been opened since manufacture.

7.2 Marking and labelling

7.2.1 Each retail unit packet shall be legibly and indelibly marked on both unit packets and outside packaging, not be obscured by any external wrapping with the following information

a) Name of the product shall be nicotine pouch

b) Name and address of the manufacturer

c) Brand name or trade name if any

d) Net weight (in grams)

e) Batch number or code

f) Manufacturing and expiry date

g) List comprising nicotine and ingredients contained in the tobacco-free oral nicotine pouches in descending order of weight. NOTE All ingredients with the main purpose of flavouring may be grouped together under the word ‘‘flavourings’’.

h) Maximum blend nicotine content {in%).

i) Allergen declarations

j) The identity of the contact sensitizer shall be indelibly printed adjacent to the ingredient list on the product labelling using the trivial name, if available, or otherwise the chemical name, as ‘‘Contains [name of the sensitizing substance].

k) Unit packets and outside packaging shall display the following warning in a clear and visible manner:

“This product contains nicotine which is a highly addictive substance.” The print shall be legible and size 17 points wordings of the warning and shall comply as same as health warning as recommended in the respective partner states Tobacco Regulation and Act.

l) Hazard category 4 Exclamation mark

7.2.2 Outside consumer packaging and unit packets shall carry information that the product is for adult consumption only, e.g. by using a symbol(s) or the following statements:

a) Keep out of reach of children; and/or

b) Sale to persons under age 18 is prohibited

c) Prohibited for children, pregnant and lactant women

Annex A

(informative)

Examples of Authoritative sources of information on the toxicological properties of compounds to be taken into account during TRAs for nicotine pouches

The following documents might include relevant information for TRAs.

A.1 Carcinogenicity classifications:

A.1.1 UN GHS:

Either category 1 or 2 via the oral route of exposure;

A.1.2 IARC either:

– “Carcinogenic to humans” (Group 1);

– “Probably carcinogenic to humans” (Group 2a); or

– “Possibly carcinogenic to humans” (Group 2b);

A.1.3 NTP as either:

– “Known”; or

– “Reasonably Anticipated To Be” human carcinogens;

A.1.1.4 USEPA IRIS as:

– “Human carcinogen” (A);

– “Probable carcinogen, limited human evidence” (B1);

– “Probable carcinogen, sufficient evidence in animals” (B2);

– “Possible human carcinogen CH - carcinogenic to humans” (C); or

– “Likely to be carcinogenic” (LH).

A.2 UN GHS germ-cell mutagen via the oral route of exposure classifications:

• Category 1;

• Category 1A; •

Category 1B; or

• Category 2.

A.3 UN GHS classifications as to toxic to reproduction via the oral route of exposure:

• Category 1;

• 1A;

• 1B; or

• effects on or via lactation.

ABBREVIATIONS

CAS number - Chemical Abstracts Service Registry Number

GRAS - FDA term for a substance “Generally Recognized by qualified experts As Safe for use in food under the conditions of its intended use”

IARC - International Agency for Research on Cancer

TRA - Toxicological risk assessment

GHS - Globally Harmonized System

NTP – United States National Toxicology Program

USEPA IRIS – United States Environmental Protection Agency Integrated Risk Information System

USP - United States Pharmacopeia

Bibliography

[1] PAS 8877:2022Tobacco-free oral nicotine pouches – Composition, manufacture and testing – Specification

[2] PS: 5468-2020 NICOTINE-CONTAINING TOBACCO FREE ORAL PRODUCT 3-(1- methyl, 2- Pyrrodinyl) Pyrindine

[3] SIS/TS 72:2020 Nicotine, tobacco free oral products – safety and quality related requirements.

[4] COOPERATION CENTRE FOR SCIENTIFIC RESEARCH RELATIVE TO TOBACCO (CORESTA). Recommended Method No. 69: Determination of pH of Tobacco and Tobacco Products