

**2.2: GLOSSARY AND ABBREVIATIONS**

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## 2.2 GLOSSARY AND ABBREVIATIONS

**Table 2.2-1: List of Glossary Terms**

<b>Term</b>	<b>Definition</b>
Adult Tobacco Consumer	Consumer can be used within a document that specifically refers to consumers of tobacco. Main idea is to be consistent within documents regarding the use of user vs. consumer
Agent-Based Modeling	Computational models for simulating the actions and interactions of hypothetical autonomous agents with a view to assessing their effects on the system as a whole
All-Cause Mortality	To avoid ambiguity or misreading, the hyphen is needed. Without a hyphen, the reader might stumble over what “cause mortality” referred to and wonder if it should be “all causes of mortality.”
Base Case	A scenario within population modeling which represents the status quo
Blending And Conditioning Process	USSTC blends tobacco types and grades by grower, growing region, and quality to minimize variability
Burley	A light, air-cured tobacco grown primarily in Kentucky and Tennessee, and also in North Carolina, Virginia, West Virginia, Ohio, Indiana and Missouri
Carrier / Solvent	A solvent used as a diluent including, but not limited to, (b) (4) and water
Chewing Tobacco	Tobacco that is coarsely shredded and sold in pocket sized packs of loose tobacco leaves
Comet Assay	OECD In vivo mammalian alkaline Comet assay (OECD 489)
Compartmental Model	A type of mathematical model used for describing the way resources are transmitted among the compartments of a system. Each compartment is assumed to be a homogeneous entity within which the entities being modeled are equivalent
Complex Tobacco	A taste category wherein the smokeless tobacco product is designed to have a complex tobacco taste
Computational Model	Mathematical model that requires extensive computational resources to study the behavior of a complex system by computer simulation
Cyma	Blood lead, blood cadmium, blood mercury, urinary arsenic, and urinary N-acetyl-S-(2-cyanoethyl)-L-cysteine

<b>Term</b>	<b>Definition</b>
Dark Air-Cured (DAC)	A dark tobacco cured using a method similar to burley tobacco
Dark Fire-Cured (DFC)	A dark tobacco cured through direct heat derived from smoldering hardwoods
Dark Tobacco	A tobacco type used in smokeless tobacco products having thick leaves and grown primarily in Kentucky and Tennessee. Dark tobacco is either air cured (Dark Air) or fire cured (Dark Fire)
Dry Snuff	Any finely cut, ground, or powdered tobacco of less than 10% OV intended to be placed in the mouth
Dry Weight	The calculated net weight of the tobacco without water
Dual User (DU)	Someone who currently uses both ENDS products (or MST, etc.) and cigarettes
Emulsifier	An emulsion stabilizing substance, also known as a “Release Agent”
Esomar	World Association of Opinion and Marketing Research (formerly European Society for Opinion and Marketing Research)
Ever Trier	Someone who has ever tried [tobacco product], even one time; may now be a current user or nonuser
Fermentation	A (b) (4) microbially-mediated (b) (4) process
Fermented Tobacco	Smokeless tobacco produced via fermentation
Final Portion Weight	The weight of an individual portion in a packaged unit sold at retail
Fine Cut	A finely cut moist snuff produced from dried tobacco (b) (4)
Flavored	A taste category wherein the smokeless tobacco product is designed to have flavored taste that compliments the tobacco
Format	The form of the product while in the mouth of the adult tobacco consumer (i.e. loose or portioned)
Former User	Someone who has used [tobacco product] to lifetime criterion and does not use [tobacco product] now
Genotox Guidance	US FDA Guidance for Industry S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use
GP	Grandfathered Product; a product that was commercially marketed in the United States as of February 15th, 2007

<b>Term</b>	<b>Definition</b>
Heat Treatment Process	A snus production process in which steam is used to soften the tobacco and reduce tobacco-related microbes
Interior Can Coating	A paraffin compound used to coat the inside of a fiberboard can
Interior Lid Coating	A rust preventing compound used to coat the inside of a metal lid
Into-Cure Process	Stage of USSTC production that increases the tobacco %OV and applies a fermentation inoculum, salts and other ingredients to the tobacco
Loose	Composed of loose or preformed tobacco that has little to no structural integrity during use
Loose Leaf	Uncut tobacco lamina that is used to produce chewing tobacco
lx	Number of survivors at each age cohort
Master Case	The most likely outcome if marketing of the MST with a label claim in it is allowed
MCMCpack	A software package designed to allow users to perform Bayesian inference via Markov chain Monte Carlo used in R package. R is an extremely powerful language and environment for statistical computation and graphics
MCMCpoisson	A function in MCMCpack
Metropolis-Hastings Sampler	A Markov chain Monte Carlo method for obtaining a sequence of random samples from a probability distribution for which direct sampling is difficult
Micronucleus Assay/Test	OECD <i>in vivo</i> mammalian erythrocyte micronucleus assay (OECD 474)
Milled	A ground tobacco produced from either cut or uncut tobacco that is passed through a milling and screening process to achieve fine to very fine tobacco particles used to produce dry snuff or moist snuff
Modified Case	A scenario within population modeling wherein the new candidate product has been introduced
Moist Smokeless Tobacco (MST)	Fine or long cut oral tobacco that may also be manufactured in pouches
Moist Snuff	A fine or coarse cut tobacco product including fine cut, long cut, pouch, and snus having greater than 10% OV and intended to be placed in the mouth; moist snuff can be produced through fermentation or a heat treatment process
Never Trier	Someone who has never tried [tobacco product], even one time

<b>Term</b>	<b>Definition</b>
Never User	Someone who has never used [tobacco product] to lifetime criterion and does not use [tobacco product] now
Non-Probability	Sampling method in which members of population of interest do not have equal chance of selection into a study
Nonusers	Someone who doesn't report using tobacco product now. They may or may not have ever tried tobacco, or may or may not have used [tobacco product] to lifetime criterion. Nonusers include former users and never users.
Oven Volatiles (OV)	Those volatiles in a tobacco or tobacco product that are evolved by treatment in a forced draft oven at a prescribed temperature for a standard period of time
Overs	Cut and dried tobacco that is larger than the mesh size of the sieve in the sifter
pH	Potential of Hydrogen - numeric scale used to specify acidity or basicity of aqueous solutions
Physics-Based Modeling	Modeling based on physical principles
Portioned	Composed of loose or preformed tobacco that utilizes materials to maintain its structural integrity during use
Postmarket	Time period after a market authorization pertinent to the product in receipt of the authorization
(b) (4)	(b) (4)
Processing Aid	Material used to facilitate processing, also known as a "Carrier", "Humectant", "Moisturizer", and "Solvent"
Product Portfolio	Products commercially marketed and/or distributed by particular entity(ies)
R Statistical Programming	R is a language and environment for statistical computation and graphics
Redrying Process	Adjusts moisture of the blended tobacco prior to packing as needed
Smokeless Tobacco	Any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity
Snus	A moist snuff, typically a pouch, produced through a heat treatment process; smokeless and spitless

<b>Term</b>	<b>Definition</b>
Stability Testing Guidance	US FDA Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products
Substrate	An inert material to which tobacco is bound in the formation of a product
Tx	Cumulative number of additional years of life lived by the additional survivors

**Table 2.2-2: List of Abbreviations**

<b>Term</b>	<b>Definition</b>
3-HPMA	3-Hydroxypropylmercapturic Acid
ABM	Agent-Based Modeling
ADF	Abuse Deterrent Formulation
ADI	Acceptable Daily Intake
ADME	Absorption, Distribution, Metabolism, and Excretion
ADP	Adenosine Diphosphate
AE	Adverse Event
AFC	Antibody Forming Cell
ALCS	Altria Client Services LLC
ANCOVA	Analysis of Covariance
APC	Aerobic Plate Count
APE	Alleged Physical Effect
AQL	Acceptable Quality Limit
AQRM	Altria Quality Requirements Manual
As	Arsenic
AS	Adult Smoker
ASNPQ	Adult Smokers Not Planning to Quit
ASPQ	Adult Smokers Planning to Quit
ASTM	American Society for Testing and Materials
ATC	Adult Tobacco Consumer
ATP	Another Tobacco Product
ATSDR	U.S. Agency for Toxic Substances and Disease Registry

<b>Term</b>	<b>Definition</b>
AUC	Area Under the Concentration-Time Curve
AUC0-inf	Area Under the Concentration-Time Curve from Time Zero to Infinity
AUC0-t	Area Under the Concentration-Time Curve from Time Zero to the Last Measurable Concentration
AUS	Actual Use Study
BAL	Bronchoalveolar Lavage
BALF	Bronchoalveolar Lavage Fluid
BaP	Benzo(a)pyrene
BLoQ	Below Limit of Quantification
BOE(s)	Biomarker(s) of Exposure
BOM(s)	Bill(s) of Materials
BOPH(s)	Biomarker(s) of Potential Harm
BUN	Blood Urea Nitrogen
CAG	Capillary Aerosol Generator
CAPI	Computer Assisted Personal Interviewing
CAS	Chemical Abstract Service
CASRO	Council of American Survey Research Organizations
CCI Study	Claim Comprehension and Intentions Study
CCP	Critical Control Point
Cd	Cadmium
CFU	Colony Forming Units
CHD	Coronary Heart Disease
CI	Confidence Interval
CIR	Cosmetic Ingredient Review
CLT	Central Location Testing
Cmax	Maximum Measured Concentration
CMC	Chemistry, Manufacturing, and Controls
Cmin	Minimum Observed Concentration
CNS	Central Nervous System
COA	Certificate of Analysis
COC	Certificate of Conformance, Consumer Opinion Center

<b>Term</b>	<b>Definition</b>
COE	Council of Europe
COHb	Blood Carboxyhemoglobin
COPD	Chronic Obstructive Pulmonary Disease
Cp	Process Capability
CPA	Crop Protection Agent
CPD	Cigarettes Per Day
Cpk	Process Capability Index
CPS-II	Cancer Prevention Study-II
CPS-TUS	Current Population Survey Tobacco Use Supplements
CRO	Contract Research Organization
CRT	Center for Research & Technology
CVD	Cardiovascular Disease
CYP	Cytochrome P450
DMBA 7,12	Dimethylbenzanthracene
DNA	Deoxyribonucleic Acid
DWB	Dry Weight Basis
EA	Environmental Assessment
EFSA	European Food Safety Authority
ELLPSS	Eurofins Lancaster Laboratories Professional Scientific Services
EMR	Excess Mortality Ratio
ERR	Excess Relative Risk
FCC	Food Chemical Codex
FCS	Former Cigarette Smoker
FDU	Former Dual User
FEMA	Flavor And Extract Manufacturers Association
FMST	Former Moist Smokeless Tobacco User
GC	Gas Chromatography
GC/FID	Gas Chromatography/Flame Ionization Detector
GC/MS	Gas Chromatography - Mass Spectrometry
GCP	Good Clinical Practice(s)
GLP	Good Laboratory Practice(s)

<b>Term</b>	<b>Definition</b>
GM	Geometric Mean
GMP	Good Manufacturing Practice(s)
GRAS	Generally Recognized as Safe
GRLs	CORESTA Guidance Residue Levels
GSD	Geometric Standard Deviation
HACCP	Hazard Analysis and Critical Control Points
HDL-C	High-Density Lipoprotein Cholesterol
HDPE	High Density Polyethylene
HINTS	Health Information National Trends
HPHC(s)	Harmful or Potentially Harmful Constituent(s)
HPLC	High Performance Liquid Chromatography
HR	Hazard Ratio
HSDB	Hazardous Substance Data Bank
HUT	Home Use Test
i.p.	Intraperitoneal
i.v.	Intravenous
IARC	International Agency for Research on Cancer
ICH	International Conference on Harmonization
ICP	Inductively Coupled Plasma
ICS	Informed Consent Statement
IOM	Institute of Medicine
IRB	Institutional Review Board
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LA	Legal Age
LC	Liquid Chromatography (LC is often used instead of "HPLC")
LC/MS/MS	Liquid Chromatography/Tandem Mass Spectrometry
LC/MS-TOF	Liquid Chromatography/Mass Spectrometry Time-of-Flight
LC50	Median Lethal Concentration
LCL	Lower Confidence Interval
LD50	Median Lethal Dose

<b>Term</b>	<b>Definition</b>
LOD	Limit of Detection
LOQ	Limit of Quantitation
LPM	Liters Per Minute
LS	Least Square
LSM	Least Square Mean
LSL	Lower specification limit
LSRO	Life Sciences Research Organization
MACS	In-Market Adult Consumer Study
MALs	USDA Expanded List Maximum Allowable Levels
MCMC	Markov Chain Monte Carlo
MedDRA	Medical Dictionary for Regulatory Activities
MMAD	Mass Median Aerodynamic Diameter
MN	Micronucleus
MPN	Most probable number
MR	Mortality rate
MST	Moist Smokeless Tobacco
MTD	Maximum Tolerated Dose
MTF	Monitoring the Future
NAB	N-nitrosoanabasine
NAT	N-nitrosoanatabine
NBW	Nicotine By Weight
NC	Not Calculated
NCI	National Cancer Institute
ND	Not Detected
NDI	National Death Index
NE	Nicotine Equivalents
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NICE	National Institute for Healthcare and Excellence
NiCr	Nickel Chromium ("NiChrome")
NIDA	National Institute on Drug Abuse

<b>Term</b>	<b>Definition</b>
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NLMS	National Longitudinal Mortality Study
NME	New Molecular Entity
NNK	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone
NNK 4'	(nitrosomethylamino)-1-(3-pyridyl)-1-butanone
NNN	N-nitrosornicotine
NOAEL	No-Observed-Adverse-Effect Level
NOEL	No-Observed-Effect Level
NPRM	Non Product-Related Material
NRC	US National Research Council
NRT	Nicotine Replacement Therapy
NSDUH	National Survey on Drug Use and Health
OECD	Organisation for Economic Co-operation and Development
OSHA	Occupational Safety and Health Administration
PADI	Possible Average Daily Intake
PAM	Pulmonary Alveolar Macrophage
PATH	Population Assessment of Tobacco and Health
PBIS	Perception and Behavioral Intentions Study
PCR	Polymerase Chain Reaction
PDE	Permissible Daily Exposure
PEL	Permissible Exposure Level
PFC	Plaque Forming Cell
PG	Propylene Glycol
PI	Principal Investigator
PII	Personally Identifiable Information
PK	Pharmacokinetic
POS	Point of Sale
PP	Polypropylene
PQRI	Product Quality Research Institute
PUMS	Public Use Microdata Sample

<b>Term</b>	<b>Definition</b>
QA	Quality Assurance
QMS	Quality Management System
QSU	Questionnaire on Smoking Urges
RCP	Royal College of Physicians
REALM	Rapid Estimate of Adult Literacy in Medicine
REL	Recommended Exposure Limit
RH	Relative Humidity
RR	Relative Risk
s.c.	Subcutaneous
SAE	Serious Adverse Event
SAO/SAP	Statistical Analysis Overview/Statistical Analysis Plan
SAS	Statistical Analysis Software
SCE	Sister-Chromatid Exchange
SD	Standard Deviation
SE	Substantial Equivalence
sICAM-1	Soluble Intercellular Adhesion Molecule-1
SILS	Single Item Literacy Screening
SKU	Stock Keeping Unit
SMART	Somatic Mutation and Recombination Test
SMDM	Society for Medical Decision Making
SLT	Smokeless Tobacco
SOC	System Organ Class
SOP	Standard Operating Procedure
SPE	Solid-Phase Extraction
SPSS	Statistical Package For The Social Sciences
SS	Stainless Steel
ST	Smokeless Tobacco
STC	Standards and Testing Center
STN	Submission Tracking Number
ST-TM	Standard Test Methods
SVOC	Semi-Volatile Organic Compound(s)

<b>Term</b>	<b>Definition</b>
TAPS	Teenage Attitudes and Practices Survey
TLV	Threshold Limit Value
Tmax	Time of the Maximum Measured Concentration
TNS	Taylor Nelson Sofres
Total NNAL	Urinary 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol and its glucuronides
TOXNET	US National Library of Medicine's Toxicology Data Network
TPM	Total Particulate Matter
TSNA(s)	Tobacco Specific Nitrosamine(s)
TTC	Threshold of Toxicological Concern
TWA	Time Weighted Average
UCL	Upper Confidence Interval
UDS	Unscheduled DNA Synthesis
UPC	Universal Product Code
US DHHS	United States Department Of Health And Human Services
USDA	United States Department Of Agriculture
USL	Upper Specification Limit
USP	United States Pharmacopeia
USSG	United States Surgeon General
USSTC	U.S. Smokeless Tobacco Company
UV	Ultraviolet
VAS	Visual Analog Scale
VG	Vegetable Glycerin
VIPM	Vertically Integrated Process Management
VOC	Volatile Organic Compound
WBC	White Blood Cells
WHO	World Health Organization
YQSM	Years Since Quitting Smoking
YSM	Years Smoked