Article 9 and 10

Toxic Contents and Emissions in Smokeless Tobacco Products

FCTC
WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL
SECRETARIAT · KNOWLEDGE HUB

NICPR
NATIONAL INSTITUTE OF CANCER PREVENTION AND RESEARCH
राष्ट्रीय कैंसर रोकथाम एवं अनुसंधान संस्थान

www.untobaccocontrol.org/kh/smokeless-tobacco/

Contents

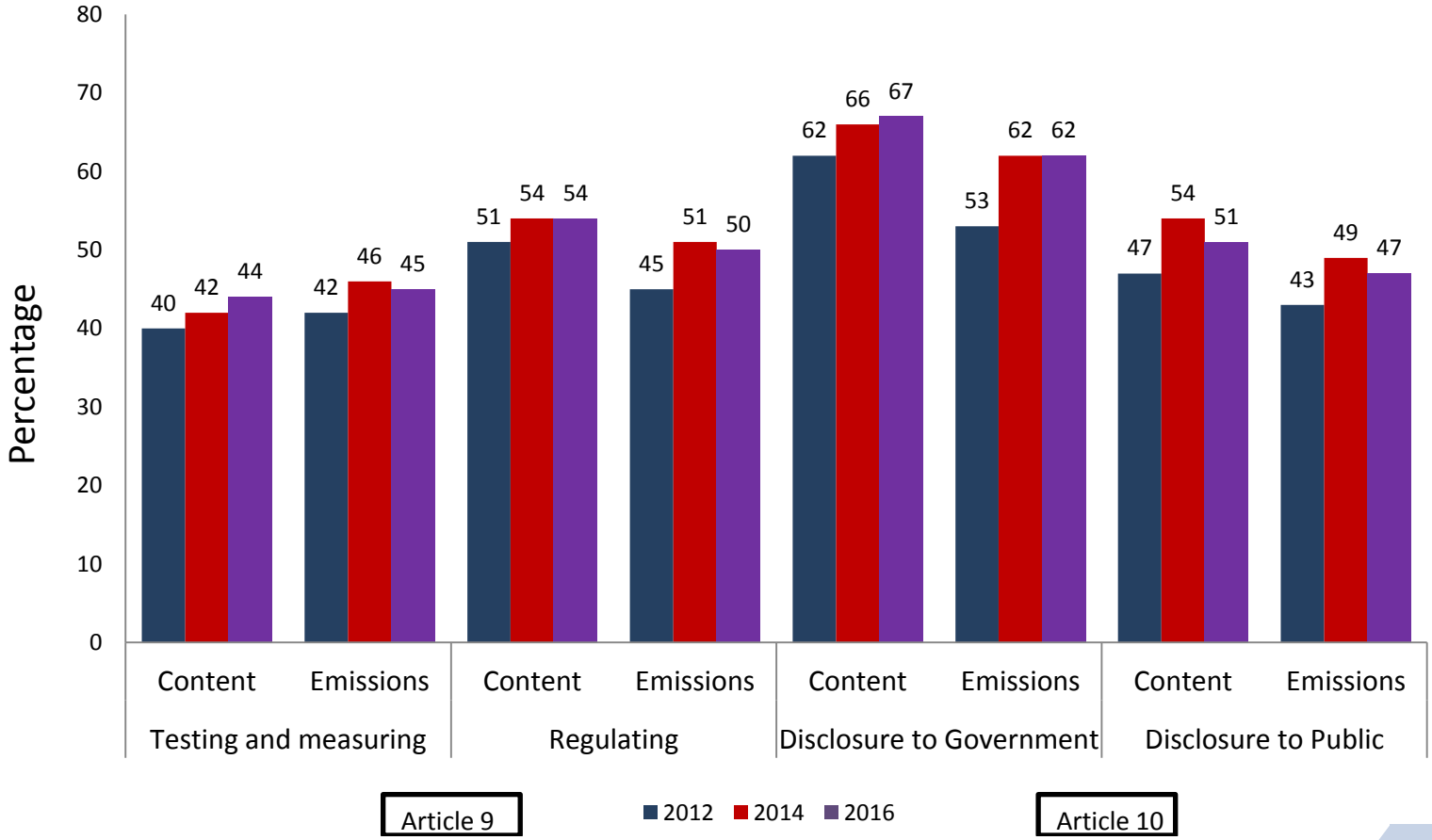
Article 9 and 10 of WHO FCTC

Article 9: Testing and measuring of the contents and emissions of tobacco products and for the regulation of these contents and emissions

Article 10: Disclosure by manufacturers and importers of tobacco products to governmental authorities of information about the contents and emissions of tobacco products, as well as for the public disclosure of information about the toxic constituents of tobacco products and their emissions.

Current Status Regarding Implementation

Percentage of Parties Implementing Provisions Under Articles 9 and 10

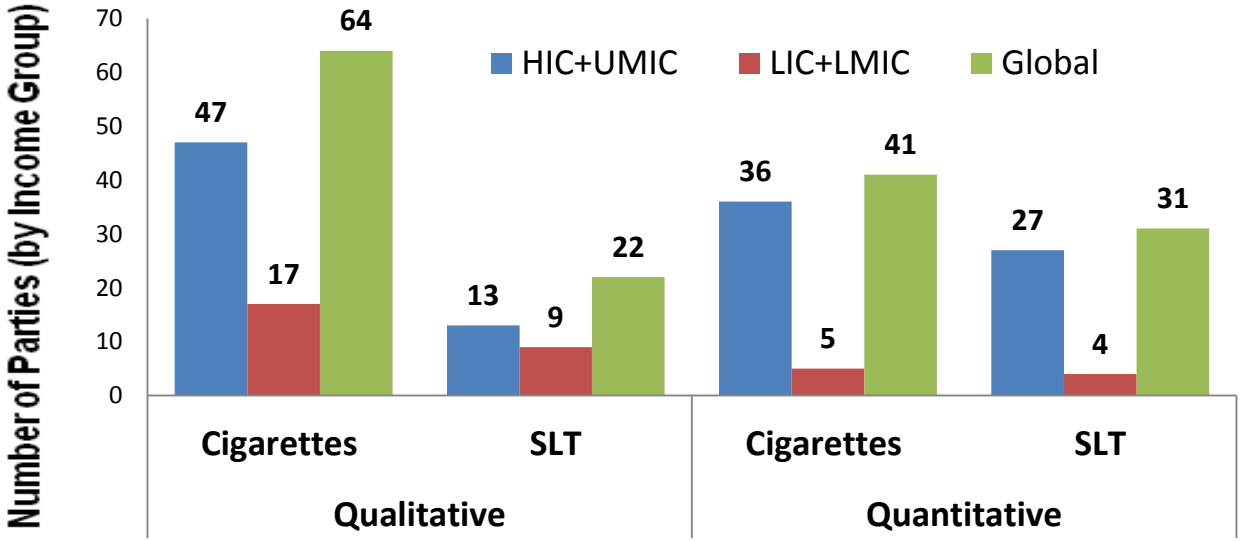


Source: Global Progress Report on implementation of the WHO Framework Convention on Tobacco Control 2014, 2016

WHO Report on the global tobacco epidemic, 2017 (MPOWER, 2017)

Does the law mandate the display of **qualitative information** on relevant constituents and emissions of tobacco products on tobacco packaging?

Does the law ban the display of **quantitative information** on emission yields (such as tar, nicotine and carbon monoxide) on tobacco packaging, including when used as part of a brand name or trademark?



Information on display for cigarette and SLT

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HIC: High income countries; UMIC: Upper middle income countries; LIC: Low income countries; LMIC: Lower middle income countries.

Law for display of quantitative and qualitative information on cigarette and

•Thirty-one Parties had law banning the display of quantitative information on emission yields (such as tar, nicotine and carbon monoxide) on SLT packaging respectively.

• In 22 Parties, the law mandated the display of qualitative information on relevant constituents and emissions of SLT packaging respectively.

•Chile, Costa Rica, Ecuador, Kenya, Nigeria, Panama, Togo and Uruguay had laws for both quantitative and qualitative display.

Chemical Constituents of SLT

- SLT products contain 4000 chemical constituents
- Composition varies according to the product, geographical location, processing and type of tobacco used
- Major classes include:
  - Alkaloids
  - Tobacco-specific N-nitrosamines
  - Poly aromatic hydrocarbons
  - N-Nitrosamino acids
  - Volatile N-nitrosamines
  - Volatile aldehydes
- Nicotine content in SLT is higher than cigarettes

Smokeless Tobacco and Some Tobacco-specific N-Nitrosamines/ IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2004 : Lyon, France) (IARC monographs on the evaluation of carcinogenic risks to humans ; v. 89); Cancer Epidemiol Biomarkers Prev. 2015 Dec;24(12):1829-37

Parties Involved in Testing of in SLT Products

10% (N=18) of the Parties have done analysis of the chemical composition of SLT on *ad-hoc* basis

- Brazil
- Canada
- Ethiopia
- Germany
- India
- Sudan
- Sweden
- UK
- South Africa
- Norway
- Pakistan
- Oman
- Ghana
- Uzbekistan
- Kyrgyzstan
- Denmark
- Turkey
- Nigeria
- USA*

*USA not a Party to convention

- All SLT products available in these Parties have not been analyzed.
- Products have not been analyzed on periodic basis

Laboratories of Parties Involved in SLT Chemical Analysis

Sweden	India
Oman	Pakistan
Nigeria	Ethiopia
Canada	USA*

*USA is not Party to the Convention

Variation in Group 1 carcinogens in SLT products of different countries

TobReg Standards

- Combine NNN and NNK <= 2 µg/g dry weight of tobacco
- Conc. Of (B[a]P) limited to 5 ng/g dry weight of tobacco

NNN and NNK

Countries	SLT Products	NNN (µg/g)	NNK (µg/g)
India	Khaini	39.4-76.9	2.34-28.4
	Zarda	4.81-19.9	3.09-16.4
	Guthka	0.09-1.09	0.04-0.43
Oman	Afzal	1.18-1.22	1.01-1.02
Sweden	Snus	0.42-3.28	0.13-1.1
Canada	Moist Snuff	0.8-6.78	0.38-2.5
Kyrgyzstan	Nasvai	1.12-1.26	0.17-0.21
Uzbekistan	Nasvai	0.59-0.69	0.07-0.07
Turkey	Maras Powder	2.2-2.8	0.63-0.77
	Iq'mik	1.99-4	0.13-0.96
USA*	Snus	0.95-5.30	0.08-0.36
	Moist Snuff	0.89-42.55	0.20-9.95
Sudan	Toombak	141-3085	188-7870
Germany	Dry Snuff	2.4-18.1	0.58-6.4

B[a]P

Countries	Smokeless tobacco products	B[a]P (ng/g)
UK	*Guthka*	0.40-1.28
	Zarda	0.32-8.89
Nigeria	Dry Snuff	0.45-9.88
USA*	*Iq'mik*	7.4-104
	Moist Snuff	0.55-106.73

***USA is not a party to convention**

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Medical Journal 2016; 16(1): e20-e26; 6. Review of the Scientific Literature on Snus (Swedish Moist Snuff), ENVIRON International Corporation Arlington, Virginia, July 2013, Project Number:24-18132C; Regulatory Toxicology and Pharmacology 2009; 53(2): 121-33; Tob Control 2017;26(3): 355-56;Indian Journal of Medical Research and Pharmaceutical Sciences, 2015, 2(11);4.; Tob Control. 2006;15(1):64-67; Cent J. 2013; 8;7(1):151; . Methods, 2015, 7, 1590-1599

Variation of Chemicals in SLT Products from India

SLT Products	Nicotine (mg/g)
Chewing Tobacco	2.6-4.1
Mishri	3.3-21
Tambaaku	8.3-22.5
Guthka	1.23-6.82
Kadipudi	4.9-5.7
Zarda	13.8-65
Khaini	19.6-21.3
Creamy Snuff	4.71-7.71

Global Nicotine Reduction Strategy (WHO TobReg), 2015

Nicotine addiction threshold <= 0.4 mg/g of dry wt. cigarette tobacco filler

Indian J Cancer 2012;49:364-72, Smokeless Tobacco and Public Health in India, Ministry of Health and Public Welfare, Government of India;

Summary

- Thirteen-one Parties have law banning the display of quantitative information on emission yields on SLT packaging respectively
- Laws of 22 Parties mandate the display of qualitative information on relevant constituents and emissions of SLT packaging respectively
- 10% (N=18) of the Parties have done analysis of the chemical composition of SLT on *ad-hoc* basis.
- Laboratories in USA, Sweden, India, Canada, Nigeria, Ethiopia, Oman and Pakistan were involved.
- No regulation of pH, nicotine and carcinogens in SLT products as values crosses the TobReg recommendation

Efforts from WHO FCTC

WHO collaborating centers working on tobacco content

There are **16** WHO collaborating centers working on tobacco; **6** works on technical training and support

S. No.	WHO Collaborating Center	Laboratory Name	WHO Region
1	WHO Collaborating Center on Tobacco Product Testing and Research, **Burkina Faso**	Laboratoire National de Santé Publique Rue Tansoba Kiém	AFR
2	WHO Collaborating Centre for Tobacco Product Regulation and Control, **Netherlands**	Laboratory for Health Protection Research	EUR
3	WHO Collaborating Centre for Tobacco Product Testing and Research, **USA**	Center for the Study of Tobacco Products	AMR
4	WHO Collaborating Centre for Tobacco Testing and Research, **Japan**	Department of Environmental Health	WPR
5	WHO Collaborating Centre for Tobacco Testing and Research, **Singapore**	Cigarette Testing Laboratory	WPR
6	WHO Collaborating Centre on Tobacco Control, **Germany**	German Cancer Research Centre	EUR

Recommendations by WHO Study Group On Tobacco Product Regulation (TobReg)

Free nicotine is absorbed more at buccal surface with higher pH

- Setting limits on free nicotine and pH

- The combined concentration of Group 1 carcinogens NNN and NNK should not be more than 2 µg/g dry weight of tobacco.

- The concentration of Group 1 carcinogen Benzo[a]pyrene (B[a]P) in SLT should be limited to 5 ng/g dry weight of tobacco.

WHO TobLabNet

Global network of government, university, and independent laboratories to strengthen national and regional capacity for the testing and research of the contents and emissions of tobacco products pursuant to Article 9 of the WHO FCTC.

Activities of TobLabNet

1. **Develop a method** for labs seeking to expand their capabilities for analysis of tobacco products and emissions.
2. **Train manpower** in analytical methods and techniques using experts.
3. **Develop common materials** for standardization, testing, and quality control.
4. **Test new methods** using multiple labs to determine robustness and applicability

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Major developments of COP7

- SOPs of WHO TobLabNet for TSNAs, B[a]P and nicotine can be adapted or applied for SLT
- Product specific analysis needs to be done
- Develop complete guidelines for Articles 9 &10 including SLT

Recommendations

- Establishment of **tobacco testing laboratories** in every region
- Development of **SOPs for testing and measuring** contents and emissions and reporting results
- Promote **collaborations between academia,** researchers, scientists and governments
- **Cooperation and collaboration** among Parties
- Further **research on SLT products**, their ingredients and emissions

Thank You

Banning the display of quantitative information on emission yields

The quantitative information showing the quantity of tar, nicotine and other emission yields on SLT packaging may provide a wrong impression that certain SLT products with lesser quantity are better than the ones with higher. This will help in marketing of such products. Therefore, WHO recommends banning the display of quantitative information on emission yields.

Mandating the display of qualitative information on constituents and emissions

The qualitative information includes displaying the negative effects of the constituents and emissions of SLT packaging. This information should be enforced and thereby have been mandated as a recommendation by WHO to the Parties.

Emissions

Emissions are substances that are produced when the product is used and this is distinguished from "exposure", a term that in this context refers to the fraction of emissions that is actually absorbed by the user. In the case of smokeless tobacco products, emissions refer to substances released during the process of oral use (“chewing”). In the case of the cigarette and other smoked products, the term refers to the constituents of the smoke. This includes those emissions directly inhaled by the user of the product (“mainstream smoke”) and those inhaled by nonusers and users alike (“secondhand tobacco smoke”).

http://www.who.int/tobacco/sactob/recommendations/en/ingredients_en.pdf

Regulation of the contents of tobacco products and regulation of tobacco product disclosures

NNK -- Nicotine-derived Nitrosamine Ketone

NNN -- N-Nitrosonornicotine