

(d) 異なる紙巻きたばこ銘柄間の濃度の差が、単一銘柄について当該毒物を繰り返し測定した場合の差よりも実質的に大きい。

(e) ある毒物の上限の義務づけを実施する場合には、煙中の所与の毒物を低減させる技術の利用可能性。

結論

54. 締約国は、自国の市場における紙巻きたばこの含有物と排出物の監視を開始し、最終的に WHO FCTC 第 9 条に規定するように含有物および排出物を規制するに当たり、下記のリストを使用することが推奨される。この優先リストは、新しい知識が利用可能になるのに合わせて、定期的に再評価すべきである。

55. 含有物および排出物の優先リストは標準的紙巻きたばこを対象に推奨されているが、非標準的な紙巻きたばこ（スリムなど）、葉巻、水たばこ、パイプ、手巻きたばこなどその他の有煙たばこ製品にも、同じ優先排出物リストを利用することができる。

56. 含有物および排出物の監視と規制は、既存の有効な TobLabNet 手法と併せて行うべきである¹。まだ存在していない方法については、次の事項を測定するための標準化された試験方法の開発は TobLabNet が優先されるべきである。

(f) カドミウムおよび鉛の含有量

(g) 水たばこの煙中のニコチン

(h) 無煙たばこ製品中のニコチン、TSNA, B[a]P

57. 各国にはタールを規制しないことを推奨する。いくつかの締約国は規制政策にタールを含めているが、タールはたばこの煙排出物に関しては毒物の優先リストに含まれない。タールの組成は質的・量的ともに製品ごとに異なるため、有効な試験および測定に限界を生じさせるからである。

58. 「WHO FCTC 第 9 条および第 10 条施行のための部分的ガイドライン」においてすでに合意されているとおり、各銘柄ならびに各含有物および排出物のデータはたばこ産業が提供すべきであり、準拠試験の費用もたばこ業界が負担すべきであることを、ここでも繰り返し述べる。

¹ See document FCTC/COP/6/14 Add.

表 4. たばこ製品の毒性含有物および排出物の優先リスト

アセトアルデヒド	アセトン	アクロレイン	アクリロニトリル
1-アミノナフタレン	2-アミノナフタレン	3-アミノビフェニル	4-アミノビフェニル
アンモニア	ベンゼン	ベンゾ[a]ピレン	1,3-ブタジエン
ブチルアルデヒド	カドミウム	一酸化炭素	カテコール
m+p-クレゾール	o-クレゾール	クロトンアルデヒド	ホルムアルデヒド
シアン化水素	ヒドロキノン	イソプレン	鉛
水銀	ニコチン	一酸化窒素	N-ニトロソアナバシン
N-ニトロソアナタピン	4-(メチルニトロソアミノ)-1-(3-ピリジル)-1-ブタノン (NNK)	N'-ニトロソノルニコチン (NNN)	窒素酸化物 (NOx)
フェノール	プロピオンアルデヒド	ピリジン	キノリン
レゾルシノール	トルエン		

第 9 条および第 10 条部分的ガイドラインにおいて推奨される措置に関するファクトシート

59. 本報告書には附属書 1 として RIP 紙巻きたばこのファクトシートを添付し、附属書 2 としてたばこ製品の成分に関するファクトシート案を添付している。ファクトシート案は、「WHO FCTC 第 9 条および第 10 条施行のための部分的ガイドライン」で推奨されている措置に基づいて策定された。これらのファクトシートは、2014 年 1 月の第 9 条および第 10 に関する作業グループ会合で発表されて作業グループの主要ファシリテーターと共有され、この会合における討議をもとに見直しが行われた。

紙巻きたばこの含有物および排出物の試験と測定のための分析化学的手法の検証の進展

60. 本報告書の補遺として別の文書が提供される。

締約国会議による行動

61. COP は本報告書に留意し、さらに詳しい指針を提供するように求められている。

附属書 1

低延焼性 (RIP) 紙巻きたばこのファクトシート (案)

低延焼性 (RIP) 紙巻きたばことは

低延焼性 (RIP) 紙巻きたばこは「ファイヤー・セイファー (fire-safer)」たばことも呼ばれ、吸わずに放置された時に自己消火するように設計されている。ただし喫煙の健康影響に関しては、RIP 紙巻きたばこが従来の紙巻きたばこより安全ということはない。他の種類の紙巻きたばこと比較した場合の主要な有用性は、火の付いた紙巻きたばこに起因する火災を防ぐ低着火性である。

従来の紙巻きたばこは、人がそばを離れて放置した場合も火が消えないように設計されている。このため、火が付いている間にマットレスや布張り家具その他の可燃物の上に落ちれば、高い発火性を発揮して不幸な結果をもたらすことになる。多くの国で喫煙は火災の主要な原因の一つであり、推定で世界の火災死亡者数の 10%を生み出している¹。喫煙が生み出す世界の火災コストは年間 272 億米ドルと推定されている。²⁷

紙巻きたばこの延焼性を規制するメリット

結局のところ、喫煙による火災発生率や火災関連死亡率を減らす最も有効な方法は、喫煙者の総数と、市場で販売する可燃性たばこの数量を減らすことである。とはいうものの、紙巻きたばこに対する防火技術基準を導入し、そうした基準への準拠を確保する法令を採択すれば、かなりの数の死傷者や物的損害を防ぐのに役立つだろう。実際、RIP 基準の実施によって喫煙材起因の火災死亡者に目に見える減少をもたらせることを示唆する十分な証拠がある。米国防火協会の 2013 年の報告書では、「2003 年から 2011 年にかけて喫煙材火災死亡が 30% 減少した主な理由」と、喫煙材関連火災事故および死者数が 1980 年以降最低レベルになっている重要な要因は、米国各州が RIP 基準を採用したことにあるようだとし唆している²。エストニアでは、2012 年に喫煙材に起因する火災の死者数が 73 人から 54 人に減少した³。この 2012 年は、RIP 紙巻きたばこ以外の市販を認めない法律が初めて通年実施された年だった²⁹。最後に、マサチューセッツ州では 2008 年に「たばこ火災予防法」(Cigarette Fire Safety law) が採択されたのにもない、住宅火災の発生確率が 28%低減した⁴。

火災の原因になりにくい紙巻きたばこの作り方

紙巻きたばこの延焼性を低減させる一般的な方法としては、包装紙の特性を変える、紙巻きたばこの太さや密度を減らす、シガレットペーパーに消火帯 (extinguishing bands) をつけるといった方法がある。延焼性を低減するのに最もよく使われているのが、消火帯を使用する方法である。消火帯法では、従来のシガレットペーパーに極薄の同心バンドを巻く。こうしたバンドは、くすぶっている燃え残りに送られる酸素を制限することによって、紙巻きたばこが吸われていないときに自然に消えるようにするものである⁵。たばこ産業は 1990 年

¹ Leistikow B, Martin DC, Milano CE. Fire injuries, disasters, and costs from cigarettes and cigarette lights: a global overview. *Preventive Medicine*. 2000;31(2):91-99.

² Hall JR. The smoking-material fire problem. Quincy (MA): National Fire Protection Association; 2013 (p. 54).

³ 2013 WHO tobacco product survey unpublished country reported data.

⁴ Alpert H, et al. Population effectiveness of cigarette ignition propensity standards. *American Journal of Public Health*. 2013. Under review.

⁵ Connolly G, Alpert HR, Rees V, Carpenter C, Wayne GF, Vallone D et al. Effect of the New York State cigarette fire safety standard on ignition propensity, smoke constituents, and the consumer market. *Tobacco Control*.

代初頭から科学的基礎と技術を進歩させ、すべての紙巻きたばこについて火災を引き起こす可能性を低減してきたが、RIPブランドを売り始めたのは2000年ごろになってのことだった¹。

低着火強度の試験と改良耐火性紙巻きたばこ (modified fire resistant cigarettes) の生産に対する技術標準が策定されている。例としては、米国材料試験協会 E2187 (紙巻きたばこの着火強度測定用標準試験法)、欧州標準化委員会の規格 CEN: EN 16156:2010 (紙巻きたばこ — 延焼性評価 — 安全要求事項)、オーストラリア規格 AS 4830-2007 (紙巻きたばこの消火性の測定)、アメリカ国立標準技術研究所の NIST SRM 1082 (紙巻きたばこ着火強度規格) および NIST SRM 1196 (着火耐性試験用標準紙巻きたばこ)、国際標準化機構の ISO 12863 (紙巻きたばこの延焼性評価用標準試験法) が挙げられる。こうした標準はさまざまな国で採用されている。

低延焼性基準を実施している国

現在、全米50州、オーストラリア、カナダ、アイスランド、南アフリカ 全28EU加盟国が、RIP紙巻きたばこを義務づける政策を採択している。これらの国は世界人口の約20%を占め、世界で製造される紙巻きたばこの約20%を消費しており、全体として高所得の大国がほとんどである²。

RIP法令の規制の枠組は、国によって異なる。カナダは公衆衛生法の範囲内で延焼性低減策を講じているのに対し、オーストラリアと米国のほとんどの州は火災予防関連の法律内で低減措置を実施している。EUでは、消費者保護法令の枠組内で同様の措置が実施されている。

科学的証拠によれば、従来の非RIP紙巻きたばこの使用者と比較した場合、RIP紙巻きたばこの使用者に喫煙行動 (吸煙量、吸煙時間、吸煙間隔など) の変化や、火災リスク関連行動 (紙巻きたばこに火がついたままの状態ですばを離れる、寝たばこなど) の増加は見られない³。加えて、排出物に関する研究は、従来の紙巻きたばことRIP紙巻きたばこの間に実質的な差異を見出さない傾向にあり⁴、リスク評価研究からは、喫煙者に毒物曝露が増加するという証拠は示されていない³³。最後に、経済研究の結果を見る限り、たばこ産業の主張⁵に反して、紙巻きたばこの防火基準の実施後に紙巻きたばこの売上高は低下していない⁶。

紙巻きたばこの延焼性の規制において政府ができること

2005;14:321-7. doi:10.1136/tc.2005.011759.

¹ Gunja M, Ferris Wayne G, Landman A, Connolly G, McGuire A. The case for fire cigarettes made through industry documents. *Tobacco Control*. 2002;11:346-53. doi:10.1136/tc.11.4.346

² Connolly GN, O'Connor RJ. Research and monitoring and scientific development with respect with respect to Reduced Ignition Propensity cigarettes. Prepared for the 7th Meeting of the WHO Study Group on Tobacco Product Regulation, Rio de Janeiro, Brazil, 3-5 December, 2013.

³ O'Connor RJ, Bauer JE, Giovino GA, Hammond D, Hyland A, Fong GT et al. Prevalence of behaviors related to cigarette-caused fires: a survey of Ontario smokers. *Injury Prevention*. 2007;13:237-42. doi:10.1136/ip.2006.013391

⁴ Pang Y. et al. Effects of low ignition propensity cigarette paper on deliveries of harmful components in mainstream cigarette smoke. *Tobacco Science and Technology*. 2013;2:52-6 (in Chinese)..

⁵ Advisory note on "fire-safer" cigarettes: approaches to reduced ignition propensity. Geneva, World Health Organization; 2008 (WHO Technical Report Series, No. 951, pp.17-32; http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf).

⁶ Connolly G, Alpert HR, Rees V, Carpenter C, Wayne GF, Vallone D et al. Effect of the New York State cigarette fire safety standard on ignition propensity, smoke constituents, and the consumer market. *Tobacco Control*. 2005;14:321-7. doi:10.1136/tc.2005.011759.

効果的なたばこ製品規制は、たばこ製品の魅惑性の低減、その依存性の低減または全体的な毒性の低減によって、たばこに起因する疾病や早死の減少に貢献できる。これまでのところ、WHO FCTC 締約国は、条約第 9 条および 10 条に規定する措置の一部を施行するための部分的ガイドラインを採択している。¹ このガイドラインでは、次の事項を実施することによって、紙巻きたばこが火災を引き起こす可能性を減らすよう締約国に促している。

- 当該方法に従って試験を行ったときに、根元まで全部燃えてしまわない紙巻きたばこの割合に関して、少なくとも現在の国際的慣行に一致する性能基準を設定する。
- たばこ製造者に対し、着火強度の試験の実行、試験結果の担当当局への報告および措置の実施費用の負担を義務づける。
- すべての紙巻きたばこに RIP 基準への準拠を義務づけ、必要な実施機構を確立する。ただし —
- RIP 紙巻きたばこは火災を引き起こさないことを示唆する主張を行わない。

RIP 法令を採択する国が増えていくと、RIP 法令が火災による死傷者の低減に与える影響に関する正確なデータを取得することが重要になる。そのためには、火災関連および紙巻きたばこ火災関連の死傷者発生傾向とパターンに関して、より標準化された比較可能な情報を集めるべきである。

要約

紙巻きたばこ火災による死者数は、喫煙による死者数よりもはるかに少ないとはいえ、対処しなければならない深刻な問題であり、また対処可能な問題でもある。少数の国は、人命を救うために自国の紙巻きたばこに対して RIP 基準を採用している。RIP 基準を採用して RIP 法を制定している国は、喫煙材起因の火災による死亡者の減少を報告している。このように、低延焼性紙巻きたばこは、公衆衛生に目に見える影響を及ぼす。RIP 法を採択し、確実な準拠のためにそれらの法律を厳しく執行すれば、製造者は必ず現在市販されている紙巻きたばこの設計を見直し、RIP 紙巻きたばこの国際基準を採用することになるだろう。たばこ産業は適正製造規範の一環として RIP 紙巻きたばこの設計を広く採用し、紙巻きたばこ起因の火災による死傷者と器物損壊を減らすべきである。

¹ *Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC*. Available at http://www.who.int/fctc/guidelines/Guidelines_Articles_9_10_rev_240613.pdf

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- Advisory note on “fire-safer” cigarettes: approaches to reduced ignition propensity. Geneva, World Health Organization; 2008 (WHO Technical Report Series, No. 951, pp.17–32; http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf).
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附属書 2

たばこ製品の成分に関するファクトシート（案）

たばこ製品の成分

たばこ製品の成分は物質、化合物、原料であり、これらが一緒に合わさってすぐに使用できるたばこ製品を構成する。

- 加工されたたばこ葉
- 加工されたたばこ葉をまとめて、通常はたばこ製品の形をつくる材料——紙やラッパー、フィルター（使用している場合）など
- たばこ葉の保管と加工に続く加工助剤および残留物
- 包装材料から製品に混入した物質
- 消費者に対する製品の魅惑性を高めるために意図的に加えられた物質。例えば、風味、製品の色や見た目を良くする物質や、たばこ製品に健康効果や活力増進効果があるという誤った印象を生み出すような物質など。

たばこ製品の製造過程で加えられる成分（防腐剤、保湿剤、香料、加工助剤を含むが、水は除く）は、添加物と呼ばれる。

たばこ製品の成分を規制することで得られるメリット

たばこ製品の成分は、その魅惑性、依存性、毒性を高めることもある。その目的による成分の使用は、WHO たばこ規制枠組条約の目的——たばこの消費およびたばこの煙にさらされることが健康、社会、環境および経済に及ぼす破壊的な影響から現在および将来の世代を保護すること——に反する。したがって、たばこ製品の成分の規制は、たばこ製品の含有物と排出物の規制ならびにその情報の関係政府当局および公衆への開示の一環として、各国の効果的なたばこ規制プログラムに不可欠である。

公衆衛生上問題のあるたばこ成分

たばこ製品の成分は、既知の有害薬物の魅惑性、依存性、毒性を高めるなど、いくつかの面で公衆衛生に影響を与える可能性がある。

魅惑性

たばこ産業は、紙巻きたばこなどのたばこ製品が既存の使用者にも潜在的使用者にもより魅力的なものになるように、さまざまな成分を使用している。製品の嫌な味や匂いを隠す、キャンディー、ガム、食品に昔からある香りを真似る、あるいは健康効果があるとか消費者の活力を増進するといった印象を与える成分は、既存の使用者に製品の継続的仕様を促したり、新しい消費者に訴えかけたりする上で重要な役割を果たす。

依存性

魅惑性を高めることに加え、依存性を最大限活用するためにさまざまな成分が意図的に操作されたり、加えられたりしている。大きな問題は、現代の紙巻きたばこは広範囲にわたり、ニコチンやその他の成分の送達装置となるように作られていることである¹。

¹ Rabinoff M, Caskey N, Rissling A, Park C. Pharmacological and chemical effects of cigarette additives. American Journal of Public Health. 2007;97(11):1981–91.

その際に、アンモニア化合物など一部の成分は、製品の嫌な味や匂いを隠すことに加えて、遊離塩基ニコチンと依存性を増やすために使用されている¹。

依存性は、オイゲノール、メントール、ココアなどの成分を加えることによって間接的に強化される場合もある。オイゲノールやメントールのような成分は喉を麻痺させて、喫煙者が煙の悪影響を感じられないような効果を持つ²。メントールはその局所麻酔性ゆえに、刺激性のあるたばこの煙をより深く吸い込むことを可能にするため、より多くの煙の吸入とより深い吸煙が行われる結果、1回の吸煙当たりのニコチン用量が多くなる³。「メントール風味の」紙巻きたばこのような製品の場合、使用者は嫌な味や香りをいつもより感じずに、より多くのたばこの煙を吸い込むことができる。したがって、メントールは爽やかさが加わるだけでなく、呼吸にかなりの生理的効果を及ぼす。同様に、ココアのような添加物が使われると気道が広がるため、煙がより簡単により深く肺に入り込み、人体がより多くのニコチンとより高レベルのタールに曝露することになる⁴。

毒性

もう一つの懸念の種は、一部の成分は単独またはたばこ製品に含まれる他の物質と組み合わせると、有毒になる恐れがあることだ。アンモニア、カフェイン、タウリンがその例である。場合によっては、美的目的で加えられる着色剤が、できあがった製品の全体的な毒性に影響を与えることもある。さらに、一部の成分には、排出される煙の粒径をはじめ、たばこの煙の物理的性質を変える能力がある。粒径は肺におけるニコチンや他のたばこ成分の吸収率に影響し、そのことが今度は血中ニコチン濃度を高めることがある⁴。さらに、成分が燃えると新たな燃焼生成物ができて、この生成物が毒性や薬理活性を持つ場合がある。重要な例の一つがアセトアルデヒドである。甘味料として加える糖分の燃焼によって産生される既知の発がん物質であるアセトアルデヒドは、ニコチンと相乗的に作用してこうした製品の依存性を強化する⁴。

たばこ製品の成分の規制と監視について国にできること

効果的なたばこ製品規制は、たばこ製品の魅惑性の低減、その依存性の低減または全体的な毒性の低減によって、たばこに起因する疾病や早死の減少に貢献できる。これまでのところ、WHO FCTC 締約国は、条約第9条および10条に規定する措置の一部を施行するための部分的ガイドラインを採択している⁵。

このガイドラインでは、たばこ製品にエネルギーや活力に関連する成分を使用することを禁止することによって、たばこ製品の魅惑性を低減させることを締約国に促している。締約国はさらに、魅惑性を低減するために、風味を増す目的で使用される成分、健康効果があるという印象を与えかねない成分、たばこ製品に着色する成分の禁止または制限を強く求められて

¹ Rabinoff M, Caskey N, Risling A, Park C. Pharmacological and chemical effects of cigarette additives. *American Journal of Public Health*. 2007;97(11):1981-91.

² Bates C, Connolly GN, Jarvis M. Tobacco additives: cigarette engineering and nicotine addiction. *Action on Smoking and Health and Imperial Cancer Research Fund*; 1999 (p. 13).

³ Addictiveness and attractiveness of tobacco additives. European Union Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Brussels: European Union; 2010 (http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_031.pdf).

⁴ Layman version on the report "Addictiveness and attractiveness of tobacco additives" (http://ec.europa.eu/health/scientific_committees/opinions_layman/tobacco/en/index.htm). See Question 5: "Do additives make tobacco more attractive?"

⁵ *Partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC*. Available at http://www.who.int/fctc/guidelines/Guidelines_Articles_9_10_rev_240613.pdf

いる。ただし、課税関連または健康被害警告の表示に使用する着色成分は除く。加えて、魅惑性を低減する措置には、WHO FCTC 第 11 条および 13 条の規定ならびにたばこ製品の包装およびラベルに関する 11 条のガイドラインとたばこの広告、販売促進および後援を禁止する 13 条のガイドラインに述べる措置を含むべきである。

さらにまたこうしたガイドラインでは締約国への勧告として、たばこ製品の製造者および輸入者に対し、自らが扱うたばこ製品の製造に使用する成分について、その成分の目的も含めた情報を政府当局に開示するよう義務づけることを求めている。この情報開示は、製品の類型別にブランドファミリー内の各銘柄につき規定の間隔で行うべきである。

たばこ産業からの強力な反対にもかかわらず、各国はたばこ成分の使用と宣伝の制限を前に進めている。例えば、ブラジルは 2012 年にメントールとその他ほとんどの添加物のたばこ製品での使用を世界で初めて禁止した。同様に、カナダは最近、国内たばこ市場における添加物およびその他の香料の広範な使用に歯止めをかけるための措置を講じている。2010 年には、他の指定成分とともにほとんどの香料がカナダ国内での使用を禁止された。EU は、たばこ製品指令を改正した。¹ この新指令の下では、特徴的なフレーバーをともなう紙巻きたばこおよび手巻きたばこは禁止されている。ビタミン、カフェインなどの特定の添加物も禁止される。この指令によって、毒性や依存効果を高める添加物の入った製品を禁止することが可能になる。加えて、特に優先リストに記載された特定の添加物に関して、たばこ産業による成分に関する電子報告が大幅に強化されている。

要約

たばこ製品の魅惑性を高める成分の使用の禁止または制限は、たばこによる疾病、苦しみおよび死亡の低減を目的として、新規および既存のたばこ使用者におけるたばこ使用率と依存性の低下に寄与できる。「WHO FCTC 第 9 条および第 10 条施行のための部分的ガイドライン」に詳述された措置の早急な採用は、各国がとるべき前向きで具体的な方策である。

¹ See <http://ec.europa.eu/health/tobacco/products/revision/>

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WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL

**Conference of the Parties to the
WHO Framework Convention
on Tobacco Control**

Sixth session
Moscow, Russian Federation, 13–18 October 2014
Provisional agenda item 4.6

**FCTC/COP/6/14 Add.1
2 September 2014**

**Progress of the validation of analytical chemical
methods for testing and measuring cigarette contents
and emissions**

Report by WHO

1. At its third session (Durban, South Africa, 17–22 November 2008), the Conference of the Parties (COP) noted the information contained in the progress report¹ of the working group on Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (WHO FCTC), and decided² to request the Convention Secretariat to invite WHO to validate, within five years, the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in the progress report of the working group, using the two smoking regimens set out in paragraph 18 of that report, and to inform the COP through the Convention Secretariat on a regular basis of the progress made. There were three priorities identified with regard to cigarette contents (nicotine, ammonia and humectants) and five with regard to emissions in mainstream smoke of cigarettes (tobacco-specific nitrosamines (TSNAs), benzo[a]pyrene (B[a]P), aldehydes, volatile organic compounds (VOCs) and carbon monoxide).

2. Of the eight methods identified, the WHO Tobacco Laboratory Network (TobLabNet) validated the methods for carbon monoxide in 2007, TSNAs and nicotine in 2010,³ and B[a]P and humectants in 2012.⁴ The standard operating procedures (SOPs) for TSNAs and nicotine⁵ were completed in 2014. WHO is currently working on the validation of methods for ammonia in cigarette tobacco filler, and

¹ Document FCTC/COP/3/6.

² See decision FCTC/COP3(9).

³ See the report by WHO's Tobacco Free Initiative to the fourth session of the COP, document FCTC/COP/4/INF.DOC./2.

⁴ See the report by WHO's Tobacco Free Initiative to the fifth session of the COP, document FCTC/COP/5/INF.DOC./1.

⁵ See http://who.int/tobacco/publications/prod_regulation/789241503907/en/

VOCs and aldehydes in mainstream cigarette smoke. This progress report contains the validation status of the three aforementioned methods.

3. After WHO has completed the validation work mandated by the COP for the methods, the SOPs and reports will be delivered shortly thereafter, depending on the availability of technical and financial resources. The publicly available final SOPs will be posted on the WHO and WHO FCTC websites.

Validation of a method for the determination of benzo[a]pyrene in mainstream cigarette smoke

4. The validation has been completed with the participation of eight laboratories, one each from Burkina Faso, Canada, China, France, Japan, Singapore, and two from the United States of America. The SOP is being finalized.

Validation of a method for the determination of humectants in tobacco

5. The validation has been completed with the participation of 13 laboratories for the Gas Chromatography Flame Ionisation Detection (GC-FID) method and seven laboratories for the Gas Chromatography Mass Spectrometry (GC-MS) method. The validation was successfully completed on two analytical instrumentation platforms, namely SOP 06: GC-FID, and SOP 06 bis: GC-MS. The humectants method validation was led by Burkina Faso and China, with the China National Tobacco Quality Supervision and Test Centre (CNTQSTC) performing the data processing and statistical analysis, with support from WHO and US Centers for Disease Control and Prevention. One of the humectants, triethylene glycol, was not detected in the reference cigarettes, so two cigarette samples with different levels of triethylene glycol were manufactured and supplied by China during the method validation process. The participating laboratories for GC-MS were from Burkina Faso, China, Greece, Japan, Singapore, and two from the United States. The participating laboratories for GC-FID were from Burkina Faso, Canada, two from China, France, Germany, Greece, Japan, Singapore, Spain, the Netherlands, and three from the United States. The laboratories from Burkina Faso, China, Greece, Singapore, and two laboratories from the United States participated in both validations. The SOP is currently being finalized.

Validation of a method for the determination of ammonia in tobacco

6. As a result of some technical challenges, the ammonia method validation is behind schedule. As reported before (in document FCTC/COP/5/INF.DOC./1), TobLabNet agreed to forego the enzymatic approach and start developing an ion chromatography technique for the ammonia validation. The validation was unable to proceed as planned in 2013 due to difficulties in finding laboratories with the necessary equipment to run the validation. Eventually, in February 2014, TobLabNet managed to gather eight laboratories to participate in this validation. The full validation started in June 2014 and the results are expected to be obtained in October 2014. The participating laboratories are from Canada, two from China, Greece, Indonesia, Japan, Spain, and the United States.

Validation of a method for the determination of volatile organic compounds and aldehydes in tobacco smoke

7. The National Institute of Public Health (NIPH) in Japan has invented a novel technique to trap both VOCs and aldehydes in cigarette smoke. This innovation consists of using one trapping material – Carboxen 572 ® which is a type of treated carbon.¹ Adaptation was needed to apply this novel technique to rotary and linear smoking machines. Colleagues from CNTQSTC and Laboratoire

¹ Uchiyama S, Tomizawa T, Inaba Y, Kunugita N. Simultaneous determination of volatile organic compounds and carbonyls in mainstream cigarette smoke using a sorbent cartridge followed by two-step elution. *Journal of Chromatography A*. 2013;1314:31–7.

of National Essais (LNE) in France adapted this new technique by re-designing the trap to enable it to be used in smoking machines. China supported the preparation of this device and distributed it to participating laboratories to carry out this validation work. Extra time was needed for research and development on the pad/cartridge holder and as a result of the logistics involved in the manufacture and assessment of each pad/cartridge holder. The adaptation was made possible with good cooperation and significant efforts by LNE in France, CNTQSTC in China, NIPH in Japan, and the National Institute of Public Health in the Netherlands. With the ammonia validation now in progress, validation of VOCs and aldehydes will resume after completion of the ammonia validation. The participating laboratories are from Burkina Faso, Canada, two from China, France, Japan, Singapore, the Netherlands, and the United States.

8. At the seventh meeting of the WHO Study Group on Tobacco Product Regulation in December 2013 in Rio de Janeiro, Brazil, it was recommended that among methods that do not exist yet, priority should be given to the development by TobLabNet of standardized testing methods for the measurement of:

- (a) cadmium and lead content in tobacco;
- (b) nicotine in smoke of waterpipe (shisha); and
- (c) nicotine, TSNAs, and B[a]P in smokeless tobacco products.¹

Action by the Conference of the Parties

9. The COP is invited to note this report.

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¹ See document FCTC/COP/6/14.



WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL

Conference of the Parties to the WHO Framework Convention on Tobacco Control

Sixth session
Moscow, Russian Federation, 13–18 October 2014
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FCTC/COP/6/9
28 May 2014

Control and prevention of smokeless tobacco products

Report by WHO

Introduction

1. This document was prepared in response to the request made by the Conference of the Parties (COP) at its fifth session (Seoul, Republic of Korea, 12–17 November 2012) to the Convention Secretariat to invite WHO to:

- identify, examine and collect existing best practices on prevention and control of smokeless tobacco (SLT) products;
- collate existing research, explore the research gap and identify the research areas that need to be focused upon; and,
- identify options for the prevention and control of SLT products.¹

2. Prior to the above request being made, the COP had reviewed, at its fourth session, a document² on this matter and subsequently requested that a comprehensive report based on the experience of the Parties on SLT be submitted to its fifth session.³ That report was duly submitted to the COP at its fifth session,⁴ and the present report should be seen as complementary to it.

3. In addition, this report incorporates the December 2013 deliberations and scientific recommendations on SLT by the WHO Study Group on Tobacco Product Regulation (TobReg),⁵ and analysis from the recent WHO survey on tobacco products. The survey was conducted between

¹ See decision FCTC/COP5(10).

² Document FCTC/COP4/12.

³ See decision FCTC/COP4(14).

⁴ Document FCTC/COP/5/12.

⁵ See http://www.who.int/tobacco/industry/product_regulation/tobreg/en/

November 2013 and April 2014 among all WHO Member States; 90 of them responded, representing 77% of the world's population. Four of them were States non-Parties to the Convention.¹

4. Documents FCTC/COP/4/12 and FCTC/COP/5/12 reviewed the definition, types, carcinogenic content, presentation and prevalence of SLT products. They also outlined the experiences of the Parties with respect to such products. This report provides expanded and up-to-date knowledge obtained from Parties' experiences and recommendations from the TobReg experts on research gaps and needs.

5. Understanding the use and impact of SLT products is complicated by the diversity of products and related behaviours that exist. Many different SLT products with different characteristics are in use around the world, including chewing tobacco, snuff, gutka, betel quid with tobacco, snus, toombak, iqmik and tobacco lozenges. Yet limited data are available on the properties of these products, how they are used, and their prevalence within different population groups. This diversity makes it difficult to make generalizations about such products as a class.

6. SLT use has received less attention than cigarette use by the global public health community because it has been perceived to impose a smaller burden on human health and was previously mainly confined to a few South Asian countries, some Nordic countries, and the United States of America. However, the problem of SLT use is no longer a local or regional problem but a major global one affecting a large percentage of the world's population.

Results of the WHO survey

7. The results of the WHO survey are shown below; figures in parentheses that follow the numbers of countries represent the percentage of the world's population living in those countries:

- (a) SLT products are regulated under tobacco laws in 46 countries (26%), both tobacco and food safety laws in 8 countries (19%), and under other laws in 9 countries (23%); in the rest, it is not known under which the laws SLT products are regulated.
- (b) Production, distribution, and sale of SLT products are under some regulation in 54 countries (66%). The number of countries that regulate the production, distribution, and sale of commercially manufactured SLT products is 41 (60%), 43 (59%) and 51 (63%), respectively. The number of countries that regulate the production, distribution, and sale of cottage industry manufactured SLT products is 24 (31%), 30 (33%) and 36 (41%), respectively.
- (c) Contents and ingredients of SLT products on the market are regulated in 9 countries (22%).
- (d) Governmental sale licences are required in 26 countries (30%).

¹ The WHO tobacco products survey on smokeless tobacco products, electronic nicotine delivery systems, reduced ignition propensity cigarettes, and novel tobacco products was sent to all WHO Member States. A total of 90 countries, including 86 Parties to the WHO FCTC, had responded to the survey as of 9 April 2014. These countries are: Australia, Austria, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Bhutan, Botswana, Bolivia (Plurinational State of), Brazil, Brunei Darussalam, Cambodia, Canada, Chile, China, Colombia, Congo, Costa Rica, Croatia, Czech Republic, Djibouti, Dominica, Ecuador, Egypt, Estonia, Fiji, Finland, France, Gabon, Georgia, Ghana, Guatemala, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Jamaica, Japan, Jordan, Lao People's Democratic Republic, Latvia, Lithuania, Kenya, Kuwait, Lebanon, Malaysia, Maldives, Mali, Mauritania, Myanmar, Mongolia, Morocco, Netherlands, New Zealand, Nicaragua, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Philippines, Poland, Qatar, Republic of Korea, Russian Federation, Slovakia, South Sudan, Spain, Sudan, Suriname, Sweden, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkey, Tuvalu, Uruguay, United Arab Emirates, United States of America, Uzbekistan, Viet Nam, Zambia.

- (e) Policies regulating sale of SLT products to minors exist in 64 countries (72%). Where specified, minimum required age for buying SLT products ranges from 16 to 21 years.
- (f) Comprehensive bans on SLT product advertising, promotion and sponsorship are in place in 50 countries (38%).
- (g) SLT product taxes are implemented as follows:
 - (i) no excise tax in 24 countries (13%);
 - (ii) uniform ad valorem excise tax in 8 countries (21%);
 - (iii) uniform specific excise tax in 11 countries (8%);
 - (iv) mix of uniform ad valorem and uniform specific excise taxes in 4 countries (2%);
 - (v) uniform ad valorem with minimum specific floors in 3 countries (1%);
 - (vi) tiered system in 1 countries (1%);
 - (vii) value added tax in 34 countries (53%);
 - (viii) import duty in 31 countries (53%).

Current regulation at the regional/country level

8. WHO African Region: In the last decade or so, the introduction of SLT products into many eastern and southern sub-Saharan African countries has mostly gone unnoticed by health and revenue authorities. A number of countries in the Region are now adopting comprehensive tobacco control policies and legislation that cover all tobacco products, including SLT products. In the United Republic of Tanzania, the sale of SLT products was banned in 2006, although it has been suggested that more stringent monitoring and enforcement are needed. Seychelles has legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

9. WHO Region of the Americas: In Brazil, SLT products are allowed for sale if they are registered with the national health regulatory agency, ANVISA. However, since none are registered, SLT products sold in Brazil are illegal. In Canada, SLT products generally fall under the broader tobacco products regulation, including prohibition of sale to minors, restrictions on promotion, and requirements for manufacturer reporting. Labelling regulations for SLT products exist but only apply to chewing tobacco, nasal snuff, and oral snuff. In the United States, laws have been enacted which include provisions for product registration, warning labels on all products, enforcement of a minimum age of sale, and limits on the amount of nicotine, toxicants, and additives. Many countries in the Region, such as Chile, Costa Rica, Ecuador, El Salvador, Honduras, Nicaragua, Panama, Peru and Uruguay, have legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

10. WHO Eastern Mediterranean Region: While Bahrain and the United Arab Emirates have adopted policies banning the sale and importation of SLT products, relevant regulatory controls are mostly absent in the Region. Heavy fine-based measures have been used to enforce the laws where present. Many countries in the Region, such as Egypt, Islamic Republic of Iran, Kuwait, Morocco, Oman, Qatar, and United Arab Emirates, have legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

11. WHO European Region: The European Union (EU) provided leadership on regulatory practices, including through the recently revised Tobacco Products Directive that governs the manufacture, presentation and sale of tobacco and related products. EU member countries regulate SLT products by prohibiting the sale of tobacco for oral use, which includes all products for oral consumption made of tobacco except those intended to be smoked or chewed. Sweden, however, is exempted from this regulation. In many eastern European Parties, SLT is regulated in accordance with advertising and health warning regulations similar to those applicable to smoked tobacco products. Turkey has legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

12. WHO South-East Asia Region: Many Parties in the Region have initiated steps to regulate SLT. Bhutan introduced a policy to ban the manufacture and sale of tobacco products, including SLT products, in 2004 and in 2010 introduced comprehensive legislation to implement the 2004 policy. India invoked food safety laws in 2011 to ban gutka and pan masala containing tobacco, some of the most common forms of SLT used in the country. India also strengthened pictorial health warnings and used intensive mass media campaigns to inform people of the harms of SLT. The country also introduced SLT cessation into tobacco dependence treatment guidelines and into the National Tobacco Control Programme. In the area of illicit trade, India introduced presumptive taxes on SLT, based on production capacity, and revenue collection on SLT products has increased more than fourfold in the last five years. Nepal has legally mandated pictorial health warnings covering 50% or more of the principal display areas on SLT packaging. In 2013, Bangladesh introduced comprehensive tobacco control legislation that includes SLT. However, the countries of the Region lack adequate laboratory testing capacity to test for constituents of SLT.

13. WHO Western Pacific Region: In 2010, concerned by the increasing use of areca (betel nut) and chewing tobacco,¹ the WHO Regional Office for the Western Pacific supported the countries in the Region in the development of a regional action plan, identifying specific tobacco control indicators and actions related to the reduction of betel nut and tobacco use. In 2012, the report by the Regional Office, prepared in consultation with countries and territories² experiencing high betel nut and chewing tobacco burdens, recognized the widespread use of betel nut in the region³ and identified the need to increase the sharing of evidence of the harms caused by this SLT sub-type with policy-makers, and also the need to develop community-based strategies to bring about changes in behaviour towards SLT use.⁴ Some Parties, such as Singapore, have banned SLT products, for example chewing tobacco, new forms of tobacco derivative products such as dissolvable tobacco, and nicotine-based products. Singapore has a laboratory for measuring nicotine content in SLT products such as chewable tobacco, betel quid, and khaini. Mongolia and Viet Nam have implemented pictorial health warnings covering 50% or more of the principal display areas on SLT product packaging.

Priority research needs

14. Until now, there has been limited research on SLT products and more relevant and specific data are needed on SLT use⁵ and the adverse health and economic costs of such use. Parties to the WHO FCTC, WHO and academic institutions have important roles to play in developing a deeper evidence base on the individual and social risks of different types of SLT. Current data- and information-gathering tools at all levels need to be adapted to collect more information on SLT.

15. Surveillance and monitoring: Comprehensive surveillance is needed to assess the scope of SLT use and changes in patterns of use, and to evaluate the impact of policies, interventions and other steps that could be taken to address SLT use, even in those Parties where SLT is banned or prevalence is very low. Surveillance and monitoring of trends in SLT use should include information on populations and subpopulations that use SLT, types of products used, rate of initiation of SLT and trajectory of tobacco use, patterns and intensity of use, combined use of other tobacco products, and

¹ Betel nut and tobacco, chewed together, is the most popular form of SLT in the WHO Western Pacific Region.

² Cambodia, Guam, Kiribati, Marshall Islands, Micronesia (Federated States of), Mariana Islands, Palau, Solomon Islands, and Vanuatu.

³ The report states that the use of betel nut “is widespread in parts of Melanesia, principally Papua New Guinea, Solomon Islands, the Northern Province of Vanuatu and in the Federated States of Micronesia, particularly in Guam, Palau, the Commonwealth of the Northern Mariana Islands and the Marshall Islands.”

⁴ The report is available from <http://www.wpro.who.int/tobacco/documents/betelnut.pdf>

⁵ Even data from Euromonitor International, which obtains its information from industry reports, show that there are just 14 out of 201 countries and territories with available records on tonnes of SLT sold in their country/territory, regardless of whether the SLT was made available by a local manufacturer or importation.

attitudes to, beliefs about and perceptions of tobacco products. Additionally, surveillance should include monitoring of changes in use and cessation of other tobacco products, including cigarettes.

16. **Economics and marketing:** There are only limited economic data available, including on pricing, tax structures and sales, to devise SLT taxation and pricing policies and programmes for different Parties. Data on SLT product marketing strategies are also very limited and information on the cost of health care to treat SLT-related disease is non-existent.

17. **Product characterization:** Given the diversity of products, modes of preparation, and scale of production around the world, a more comprehensive characterization of the properties of different products, their constituents, and methods of manufacture is needed. Additionally, attention should be given to estimating the health impact of carcinogenic non-tobacco products that are frequently used in conjunction with tobacco, such as areca nut (betel nut). Testing of products must occur regularly in order to assess national and regional variations and any changes in products over time.

18. **Health effects:** Despite the differences in the relative risks of the various SLT products, no SLT product is safe. However, the diversity of products, practices, and patterns of use precludes broad generalizations about the health effects of SLT use. Most studies of health effects have been conducted in Scandinavian countries, the United States, and India. There is a need to carry out product-specific and country-specific assessments of the health burden of SLTs products to determine the global disease burden.

19. **Interventions:** Population-based prevention and individual cessation interventions need to be tailored to SLT users, taking into account the heterogeneity of SLT products and their addictiveness. The use of mobile technology (mCessation) to reach the target population groups, along with the adoption of other cessation support services in primary health care settings, needs to be looked into. Furthermore, as most of the current evidence base for the effectiveness of cessation interventions comes from smoking cessation experiences in high-income Parties, there is a need for further research on development and evaluation of interventions for SLT cessation in low- and middle-income Parties.

Regulatory options for prevention and control of SLT products

20. **Develop Party-specific and product-specific interventions:** Comprehensive implementation of the WHO FCTC for regulating all tobacco products, including SLT products, is vital to the regulation of SLT products. However, given the heterogeneity of SLT products, there may be a need for product-specific policy interventions and strategies that fit the context of local community, prevalence rates, etc. For example, for some Parties, banning sales of and trade in all, or the most prevalent forms of, SLT products may be appropriate.

21. **Apply WHO FCTC requirements to SLT products:** Tobacco control policy interventions for cigarettes and other smoking forms of tobacco should also apply to SLT products. These interventions include: (1) health warnings on product packaging that cover the major proportion of packages, include text and pictorial warnings, are rotated, and are located on the top principal display areas; (2) restrictions or bans on advertising, promotion, and sponsorships; (3) bans on sales to minors; (4) taxation and pricing policies, with effective compliance, to discourage SLT use and lower demand – tax-induced price increases should be high enough to reduce consumption; (5) promotion and provision of evidence-based SLT cessation interventions; (6) education of the public about the harms of SLT use through information, education, and communication efforts to boost awareness of the harmful health effects of SLT use and to dispel myths – education should be targeted at health professionals, policy-makers, community leaders and the public, through mass media and other channels.

22. In addition, Parties that are considering or in the process of ratifying the Protocol to Eliminate the Illicit Trade in Tobacco Products should also take into consideration the domestic and cross-border trade of SLT.

23. WHO TobReg has noted that the following manufacturing practices are known to lessen somewhat toxicant levels in SLT:

- (a) air curing which produces lower levels of tobacco-specific nitrosamines as compared to other methods;
- (b) pasteurization as compared to fermentation; and
- (c) avoiding storage for prolonged periods in warm weather.

These manufacturing practices do not imply necessarily reductions in human exposure, risk or disease. Regulatory options in this domain should be considered only in light of the content of the section on regulation of tobacco product toxicants of document FCTC/COP/6/14.

24. Disclose constituents of SLT products: Manufacturers should be required to disclose to governments all ingredients and harmful and potentially harmful constituents of their SLT products.

25. Reduce the appeal of SLT products by banning or regulating sweeteners and flavouring substances (including herbs, spices, and flowers) as recommended in the partial guidelines for implementation of Articles 9 and 10, Section 3.1.2.2(i).¹

26. No health claims or claims of reduced exposure or harm should be allowed until scientific evidence in support of such claims has been reviewed and approved by an independent, scientific government regulatory agency.

27. Address information gaps by sharing current progress and challenges and expand the existing evidence base including the quantification of risks (burden on health, economy, environment, and social costs) by utilizing existing WHO Global Tobacco Surveillance System and WHO STEPs surveys. These surveys could be used to provide greater coverage of SLT use at the country level. Smaller, targeted surveys are also needed in order to understand patterns among specific subgroups.

28. Lack of laboratory capacity for the testing of tobacco products is a major challenge in regulating SLT products. Some countries lack the capacity to evaluate contents and toxicant levels. Despite the budget and resource limitations, improvements are needed in methods, specific product standards, and testing regimens. Testing methods should be standardized and, ideally, coordinated by region, perhaps through the WHO Tobacco Laboratory Network.²

29. Conduct impact assessments and evaluations of SLT-related policy and regulatory practices. Gathering relevant data and sharing of Parties' experiences of SLT importation and use is crucial to helping Parties adopt comprehensive, WHO FCTC compliant policies and programmes that encompass the regulation of SLT products.

ACTION BY THE CONFERENCE OF THE PARTIES

30. The COP is invited to note this report and provide further guidance.

¹ The Guidelines are available at: http://www.who.int/fctc/guidelines/adopted/article_9and10/en/

² See http://www.who.int/tobacco/industry/product_regulation/toblabnet/en/